



# County of Los Angeles **CHIEF EXECUTIVE OFFICE**

713 KENNETH HAHN HALL OF ADMINISTRATION  
LOS ANGELES, CALIFORNIA 90012  
(213) 974-1101  
<http://ceo.lacounty.gov>

**WILLIAM T FUJIOKA**  
Chief Executive Officer

February 12, 2008

The Honorable Board of Supervisors  
County of Los Angeles  
383 Kenneth Hahn Hall of Administration  
500 West Temple Street  
Los Angeles, CA 90012

Dear Supervisors:

**DEPARTMENT OF PUBLIC HEALTH: ACCEPTANCE OF  
STANDARD AGREEMENT NUMBER 07-65726 FROM THE  
CALIFORNIA DEPARTMENT OF PUBLIC HEALTH FOR THE  
PUBLIC HEALTH LABORATORY GENOTYPING PROJECT  
(ALL SUPERVISORIAL DISTRICTS)  
(3 VOTES)**

**IT IS RECOMMENDED THAT YOUR BOARD:**

1. Approve and instruct the Director of the Department of Public Health (DPH), or his designee to accept and sign Standard Agreement Number 07-65726 (Exhibit I) received from the California Department of Public Health (CDPH) to provide funding for HIV-1 Viral Resistance Testing (Genotyping Project) which will be performed by DPH's Public Health Laboratory (PHL) for the period of July 1, 2007 through June 30, 2010, at a total allocation of \$562,500 per Fiscal Year (FY) or at a total maximum obligation of \$1,687,500 for the three-year period, at no net County cost.
2. Delegate authority to the Director of DPH, or his designee, to amend the CDPH Standard Agreement Number 07-65726 for the period of July 1, 2007 through June 30, 2010, to rollover unspent funds throughout the life of the contract, to extend the term and/or increase or decrease the base award up to 25 percent, subject to review and approval by County Counsel and Chief Executive Office and notification to the Board offices.

Board of Supervisors  
**GLORIA MOLINA**  
First District

**YVONNE B. BURKE**  
Second District

**ZEV YAROSLAVSKY**  
Third District

**DON KNABE**  
Fourth District

**MICHAEL D. ANTONOVICH**  
Fifth District

### **PURPOSE/JUSTIFICATION OF RECOMMENDED ACTION**

HIV-1 Viral Resistance Testing (VRT) is comprised of a series of resistance tests performed on eligible HIV-infected individuals that allows physicians to determine the most effective combination of antiretroviral drugs for treatment/therapy.

In October 2007, DPH's PHL received Standard Agreement Number 07-65726 from CDPH in the amount \$1,687,500 for the continuation of the Genotyping Project that has expanded the program to include the provision of Virtual Phenotypic services. Genotype services will be reimbursed at \$360 per test and Virtual Phenotype services at \$145 per test.

### **FISCAL IMPACT/FINANCING**

The total allocation is \$562,500 per FY, or \$1,687,500 for the period of July 1, 2007 through June 30, 2010, 100 percent offset by CDPH funds.

Funding is included in the FY 2007-08 Final Adopted Budget and will be requested in future fiscal years.

### **FACTS AND PROVISIONS/LEGAL REQUIREMENTS**

Since the inception of the HIV Viral Resistance Program in FY 2000-01, DPH's PHL has provided genotypic testing to eligible patients in Los Angeles County. Over the years, CDPH funding has supported and sustained the continued utilization of innovative laboratory technology for those patients who require state of the art testing for HIV drug resistance to enhance treatment outcomes. The continued funding provides HIV-1 VRT to patients treated in publicly funded HIV/AIDS health care settings for whom these tests would otherwise not be available due to lack of funding.

The program operates on a fee-for-service basis utilizing State vouchers. The voucher-driven program in Los Angeles County is a joint effort between the PHL and DPH's Office of AIDS Programs and Policy, which assists with the distribution of the State vouchers to local health clinics. Vouchers are also provided to local Early Intervention Programs (EIP) by CDPH. Although genotypic testing is the preferred approach for resistance testing, the CDPH has authorized the PHL to perform virtual or predictive phenotypic testing services (beginning this contractual term), which is an additional service available to patients, and provides physicians with additional HIV drug resistance information.

Exhibit I has been approved as to form by County Counsel.

Honorable Board of Supervisors  
February 12, 2008  
Page 3

Attachment A provides additional information. Attachment B is the Grants Management Statement required for grant awards exceeding \$100,000. Attachment C is the Project Budget for the three-year period.

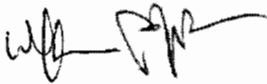
**IMPACT ON CURRENT SERVICES (OR PROJECTS)**

The recommended Board actions will provide a valuable service and enhance treatment outcomes for eligible HIV-infected patients in Los Angeles County.

**CONCLUSION**

The Department of Public Health requires four signed copies of your Board's action. It is requested that the Executive Officer, Board of Supervisors, notify the Department of Public Health, Contracts and Grants Division, at (213) 240-8179 when these documents are available.

Respectfully submitted,



WILLIAM T FUJIOKA  
Chief Executive Officer

WTF:SRH  
SAS:TOF:bjs

Attachments (4)

c: County Counsel  
Director and Health Officer, Department of Public Health

021208\_DPS\_Genotyping

## SUMMARY OF AGREEMENT

1. TYPE OF SERVICE:

The Department of Public Health (DPH), Public Health Laboratory (PHL) performs HIV-1 Resistance Testing (Genotyping Project) on specimens drawn from eligible HIV-1 infected individuals. Blood specimens are drawn at designated clinical sites and transported to the PHL for analysis to measure drug resistance.

2. AGENCY ADDRESS AND CONTACT PERSON:

California Department of Public Health  
Office of AIDS  
MS7700  
P.O. Box 997426  
Sacramento, CA 95899-7426  
Attention: Drew Young  
Office of AIDS – Contracts and Grants Unit  
(916) 449-5931

3. TERM OF AGREEMENT:

July 1, 2007 through June 30, 2010.

4. FINANCIAL INFORMATION:

The total allocation of \$562,500 per Fiscal Year (FY) or \$1,687,500 for the period of July 1, 2007 through June 30, 2010, 100% offset by CDPH funds.

Funding is included in the Fiscal Year (FY) 2007-08 Final Adopted Budget and will be requested as a continuing appropriation in future fiscal years.

5. GEOGRAPHIC AREA TO BE SERVED:

Countywide.

6. ACCOUNTABLE FOR MONITORING AND EVALUATION:

Sue Sabet, Ph.D., Laboratory Director  
DPH Public Health Laboratory

7. APPROVALS:

Public Health Programs:	Jonathan E. Freedman, Acting Chief Deputy
Contract Administration:	Gary T. Izumi, Division Chief
County Counsel (approval as to form)	Maya Lee, County Counsel

**Los Angeles County Chief Administrative Office  
Grant Management Statement for Grants Exceeding \$100,000**

Department: Public Health – Public Health Laboratory

**Grant Project Title and Description**

Public Health Laboratory Genotyping Project – To provide IV Viral Resistance Testing (Genotyping Project) to Eligible HIV Infected Clients.

Funding Agency  
California Department of  
Public Health

Program (Fed. Grant #State Bill or Code #)  
Standard Agreement No. 07-65726

Grant Acceptance Deadline  
N/A

Total Amount of Grant Funding: \$1,687,500

County Match Requirements:

Grant Period: FY July 1, 2007 - June 30, 2010

Begin Date: 7/01/07 End Date: 06/30/10

Number of Personnel Hired Under this Grant: Full Time

Part Time 0

**Obligations Imposed on the County When the Grant Expires**

Will all personnel hired for this program be informed this is a grant funded program? Yes ☒ No ☐

Will all personnel hired for this program be placed on temporary "N" items? Yes ☒ No ☐

Is the County obligated to continue this program after the grant expires Yes ☐ No ☒ --

If the County is not obligated to continue this program after the grant expires, the Department will:

a). Absorb the program cost without reducing other services Yes ☐ No ☒

b). Identify other revenue sources Yes ☐ No ☒

(Describe)

c). Eliminate or reduce, as appropriate, positions/program costs funded by this grant Yes ☒ No ☐

Impact of additional personnel on existing space: None

Other requirements not mentioned above: None

Department Head  
Signature



Date 1-9-08

LOS ANGELES COUNTY - DEPARTMENT OF PUBLIC HEALTH  
PUBLIC HEALTH LABORATORY  
STATE/OAPP GENOTYPING PROJECT  
FY2007-08

Description	# of FTE	FTE%	MONTHS	A				B	A+B	
				MONTHLY SALARY	TOTAL SALARY (7/07-12/07)	MONTHLY SALARY 3% COLA EFFECTIVE JAN. 08	TOTAL SALARY (1/08-6/08)			TOTAL OAPP GENOTYPING PROJECT
I. <u>PERSONNEL SERVICES</u>										
Clinical Microbiologist II - Deleted	1	100%	12	0.00	\$ -	\$ -	\$ -	-	\$ -	-
PH Microbiology Supervisor I	1	100%	12	6,137.00	36,822.00	6,321.11	37,926.66	74,748.66		74,748.66
PH Microbiologist II	2	100%	12	5,770.45	69,245.40	5,943.56	71,322.76	140,568.16		140,568.16
Senior Laboratory Assistant	1	100%	12	3,014.00	18,084.00	3,104.42	18,626.52	36,710.52		36,710.52
Laboratory Assistant	1	100%	12	2,708.45	16,250.70	2,789.70	16,738.22	32,988.92		32,988.92
Subtotal Salaries	6				\$ 140,402.10		\$ 144,614.16	\$ 285,016.26		285,016.26
Less: Salary Savings		10.0000%						(28,501.63)		(28,501.63)
Total Net Salaries								\$ 256,514.64		256,514.64
Employee Benefits @ 48.16% of net salary	48.1600%							123,537.45		123,537.45
TOTAL PERSONNEL										
								\$ 380,052.09		380,052.09
II. <u>OPERATING EXPENSES</u>										
Laboratory Reagents and Supplies										172,447.91
Travel										10,000.00
TOTAL OPERATING EXPENSES										
										182,447.91
III. <u>INDIRECT COST (on total net salaries)</u>										
							18.2800%			0.00
TOTAL PROJECT COSTS										
										562,500.00

**NOTE:**

- 1 State Genotyping Project: \$ 560,288.66 for FY 2007-08

LOS ANGELES COUNTY - DEPARTMENT OF PUBLIC HEALTH  
PUBLIC HEALTH LABORATORY  
STATE GENOTYPING PROJECT  
FY 2008-09

Description	# of FTE	FTE%	MONTHS	A			B	A+B	
				MONTHLY SALARY EFFECTIVE JULY08	TOTAL SALARY 2.75% HALF STEP JULY08 - DEC.08	MONTHLY SALARY 3% COLA EFFECTIVE JAN. 09	TOTAL SALARY 3% COLA JAN 09 - JUNE 09	TOTAL OAPP GENOTYPING PROJECT FISCAL YEAR 08-09	
I. PERSONNEL SERVICES									
PH Microbiology Supervisor I	1	100%	12	\$	6,321.11 \$	37,926.66 \$	6,510.74 \$	39,064.46 \$	75,852.00
PH Microbiologist II	2	100%	12		5,943.56	35,661.36	6,121.87	36,731.20	140,568.00
Senior Laboratory Assistant	1	100%	12		3,104.42	18,626.52	3,197.55	19,185.32	37,253.04
Laboratory Assistant	1	100%	12		2,789.70	16,738.20	2,873.39	17,240.35	32,988.00
Subtotal Salaries	5			\$	18,158.79 \$	108,952.74 \$	18,703.55 \$	112,221.32 \$	286,661.04
Less: Salary Savings					10.0000%				(28,666.39)
Total Net Salaries					48.1600%				257,994.65
Employee Benefits @ 48.16% of net salaries									124,250.22
TOTAL PERSONNEL									
								\$	382,244.87
II. OPERATING EXPENSES									
Laboratory Reagents and Supplies									170,255.13
Travel									10,000.00
TOTAL OPERATING EXPENSES									
								\$	180,255.13
III. INDIRECT COST (on total net salaries)									
					18.2800%				\$0
TOTAL									
								\$	562,500.00

State Genotyping Project: \$ 562,481.87 for FY 2008-09

LOS ANGELES COUNTY - DEPARTMENT OF PUBLIC HEALTH  
PUBLIC HEALTH LABORATORY  
STATE GENOTYPING PROJECT  
FY 2009-10

Description	# of FTE	FTE%	MONTHS	MONTHLY SALARY	TOTAL OAPP GENOTYPING PROJECT FISCAL YEAR 09-10
<b>PERSONNEL SERVICES</b>					
PH Microbiology Supervisor	1	100%	12	\$ 6,510.74	\$ 78,128.88
PH Microbiologist II	2	100%	12	6,121.87	146,924.88
Senior Laboratory Assistant	1	100%	12	3,197.55	38,370.60
Laboratory Assistant	1	100%	12	2,873.39	34,480.68
Subtotal Salaries	5			\$ 18,703.55	\$ 297,905.04
Less: Salary Savings		10.0000%			(29,790.50)
Total Net Salaries					\$ 268,114.54
Employee Benefits @ 48.16% of net salaries		48.1600%			129,123.96
<b>TOTAL PERSONNEL</b>				\$	397,238.50
<b>OPERATING EXPENSES</b>					
Laboratory Reagents and Supplies				\$	155,261.50
Travel				\$	10,000.00
<b>TOTAL OPERATING EXPENSES</b>				\$	165,261.50
<b>INDIRECT COST (on total net salaries)</b>		18.2800%			0.00
<b>TOTAL</b>				\$	<b>562,500.00</b>



**STANDARD AGREEMENT**

STD 213\_CDPH (7/07)

Exhibit I

REGISTRATION NUMBER

AGREEMENT NUMBER

07-65726

## 1. This Agreement is entered into between the State Agency and the Contractor named below:

STATE AGENCY'S NAME

(Also known as CDPH, CDHS, DHS or the State)

California Department of Public Health

CONTRACTOR'S NAME

(Also referred to as Contractor)

County of Los Angeles

## 2. The term of this Agreement is: July 1, 2007 through June 30, 2010

3. The maximum amount of this Agreement is: \$ 1,687,500  
One Million, Six Hundred Eighty-Seven Thousand, Five Hundred Dollars.

## 4. The parties agree to comply with the terms and conditions of the following exhibits, which are by this reference made a part of this Agreement.

Exhibit A – Scope of Work	4 pages
Exhibit B – Budget Detail and Payment Provisions	3 pages
Exhibit B Attachment I – Invoice Format	1 page
Exhibit B Attachment II – Genotypic HIV-1 Resistance Test Voucher	2 pages
Exhibit B Attachment III – Virtual Phenotypic Service Voucher	2 pages
Exhibit C * – General Terms and Conditions	<u>GTC 307</u>
Exhibit D (S) – Special Terms and Conditions (Attached hereto as part of this agreement)	18 pages
Exhibit E – Additional Provisions	2 pages
Exhibit F – Contractor's Release	1 page
Exhibit G – HIPAA Business Associate Addendum	7 pages

Items shown above with an Asterisk (\*), are hereby incorporated by reference and made part of this agreement as if attached hereto.  
 These documents can be viewed at <http://www.ols.dgs.ca.gov/Standard+Language>.

IN WITNESS WHEREOF, this Agreement has been executed by the parties hereto.

**CONTRACTOR**

CONTRACTOR'S NAME (if other than an individual, state whether a corporation, partnership, etc.)

County of Los Angeles

BY (Authorized Signature)

DATE SIGNED (Do not type)



PRINTED NAME AND TITLE OF PERSON SIGNING

Sue Sabet, Ph. D., Laboratory Director

ADDRESS

313 North Figueroa Street, Room 1127  
Los Angeles, CA 90012**STATE OF CALIFORNIA**

AGENCY NAME

California Department of Public Health

BY (Authorized Signature)

DATE SIGNED (Do not type)



PRINTED NAME AND TITLE OF PERSON SIGNING

Allan Chinn, Chief, Contracts and Purchasing Services Section

ADDRESS

1501 Capitol Avenue, Suite 71.5178, MS 1802, P.O. Box 997377,  
Sacramento, CA 95899-7377**California Department of  
General Services Use Only**
☒ Exempt per: OOA transaction is  
exempt per applicable Budget Act

**Exhibit A**  
**Scope of Work**

**1. Service Overview**

Contractor agrees to provide to the California Department of Public Health (CDPH) the services described herein.

The Contractor will provide HIV-1 Resistance Test (RT) services for the CDPH, Office of AIDS (OA), HIV Therapeutic Monitoring Program (TMP). TMP eligible clients are also AIDS Drug Assistance Program (ADAP) eligible clients from state-funded Early Intervention Program (EIP) sites and Local Health Jurisdiction (LHJ) sites. TMP utilizes a fee-for-service, voucher-based system for each type of resistance test. Services include performing HIV-1 resistance testing from plasma samples, participating in both statewide and national proficiency testing programs, and conducting additional RT related tests as needed upon prior authorization by the Office of AIDS and/or Viral and Rickettsial Disease Laboratory (OAVRDL).

**2. Service Location**

The services shall be performed at 2750 Erickson Avenue, Downey, CA 90242.

**3. Service Hours**

The services shall be provided during normal Contractor working hours, Monday through Friday, excluding state holidays.

**4. Project Representatives**

A. The project representatives during the term of this agreement will be:

<b>California Department of Public Health</b> Toni Post, Contract Monitor Telephone: (916) 449-5970 Fax: (916) 449-5959 Email: Toni.post@cdph.ca.gov	<b>Los Angeles County Public Health Laboratory</b> Sue Sabet, Ph.D., Laboratory Director Telephone: (213) 250-8619 Fax: (213) 481-2375 Email: ssabet@ladhs.org
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B. Direct all inquiries to:

<b>California Department of Public Health</b> Office of AIDS Early Intervention Section Therapeutic Monitoring Program Attention: Toni Post MS 7700 P.O. Box 997426 Sacramento, CA 95899-7426  Telephone: (916) 449-5970 Fax: (916) 449-5959 E-mail: Toni.post@cdph.ca.gov	<b>Los Angeles County Public Health Laboratory</b> Sue Sabet, Ph.D., Laboratory Director 313 North Figueroa Street, Room 1127 Los Angeles, CA 90012  Telephone: (213) 250-8619 Fax: (213) 481-2375 Email: ssabet@ladhs.org
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C. Either party may make changes to the information above by giving written notice to the other party. Said changes shall not require an amendment to this agreement.

**Exhibit A**  
**Scope of Work**

**5. Services to be Performed**

Contractor shall perform the following services:

- A. As one of six (6) approved participating resistance test (RT) laboratories under the Department's TMP, the Contractor will provide HIV-1 resistance testing services for eligible clients from state-funded Early Intervention Program (EIP) sites and Local Health Jurisdiction (LHJ) sites. RT services include the following timely activities which are reimbursable as fee-for-service under this contract: performing HIV-1 RT from plasma samples, reporting applicable genetic sequence as required, collecting and entering voucher data into an appropriate format, participating in both statewide and national proficiency testing programs, and conducting additional RT related tests as needed upon prior authorization by the Office of AIDS/Viral and Rickettsial Disease Laboratory (OA/VRDL).
- B. The overall RT program will be administered and funded by the Department's Office of AIDS and will be a coordinated effort with the Department's Viral and Rickettsial Disease Laboratory (VRDL) in Richmond.
- C. The Contractor shall perform HIV-1 genotypic resistance testing as a means of assessing resistance of HIV to antiretroviral drugs. All resistance tests shall be based upon the cDNA sequence in the Protease and Reverse Transcriptase regions of the HIV genome (genotype-based RTs), or if applicable, the activity of patient-specific recombinant HIV in the presence of different concentrations of antiretroviral drugs (phenotype-based RTs).
- D. Although genotypic testing is the preferred approach for resistance testing, the Contractor may perform virtual or predictive phenotypic testing services. A clinician may order a virtual phenotype based on the results of a recent genotypic test. The Contractor must have the capability to retrieve the client's most recent genotypic sequence (within the last 30 days) from their own database for virtual phenotyping to occur and must ensure that the test is linked by the client URN. The virtual phenotypic service uses genotypic data to determine the likely in vitro drug susceptibility (phenotype) of a patient's virus by matching the patient virus to a large database of virus with paired genotypic and phenotypic results.
- E. A virtual phenotype **should not be ordered or performed** on an antiretroviral naïve patient unless there is evidence of drug resistance. In addition, a virtual phenotype **should not be performed** if the genotype shows:
  - 1. Susceptibility (no evidence of resistance or possible resistance) to all drug classes.
  - 2. The M184V mutation conferring lamivudine (3TC) resistance only.
  - 3. Any nonnucleoside (NNRTI) mutation in the absence of resistance to other drug classes.
  - 4. The D30N mutation conferring nelfinavir (NFV) resistance only.
  - 5. Protease inhibitor polymorphisms or mutations that are not associated with resistance or possible resistance.
  - 6. Any combination of b, c, d, and e above.

Reimbursement will not occur for any specimens that do not adhere to this section.

- F. Designated EIP staff and individuals authorized by LHJ sites, following OA guidelines, shall determine client eligibility and shall complete the respective RT Voucher. Instructions for completing the RT Voucher will be provided by OA's TMP. It is the responsibility of the Contractor to review each voucher for its completeness and obtain any missing information.

**Exhibit A**  
**Scope of Work**

If samples are received with incomplete information, the Contractor shall put the test on hold until the form is completed accurately and shall preserve the integrity of the specimen. All specimens submitted to the Contractor with a completed and accurate RT Voucher shall be considered eligible for testing and reimbursement, except for virtual phenotyping. In the case of virtual phenotypic requests, the Contractor must ensure that the specimen meets the genotypic requirements **prior** to performing the virtual phenotypic test (see E above), and must retrieve the most recent sequence (within 30 days) from their database linking to the client unique record number (URN).

- G. After authorization by OA's TMP, participating EIP and LHJ sites will submit specimens consisting of two (2) tubes of frozen plasma, containing at least 1 mL each and a completed and accurate RT Voucher (**see Exhibit B Attachments**) to any one of the approved Contractors. The Contractor shall provide all necessary instructions for specimen collection and processing, including provisions for transport to the Contractor's RT laboratory and subsequent shipment of 1 frozen plasma sample to the VRDL for central repository.
- H. The Contractor shall ship 1 of the 2 frozen plasma samples, containing at least 1 mL and identified only by its client unique record number (URN), to the VRDL within 3 months of performing the RT for the central repository.
- I. The Contractor shall confirm that RT samples are processed and shipped using procedures consistent with those specified by the Contractor. The Contractor shall only perform resistance testing on samples meeting these specifications.
- J. The Contractor shall make certain that a completed RT Voucher is submitted with each RT sample. Two vouchers require completion for performing virtual phenotypic services: *Genotypic HIV-1 Resistance Test Voucher* and the *Virtual Phenotypic Service Voucher*. All vouchers shall be retained for a minimum of 4 years.
- K. The Contractor shall ensure that all test results are linked to the Client URN, which is recorded on each RT Voucher. The Contractor will not be reimbursed for tests performed on samples not linked to a Client URN.
- L. The Contractor shall report RT results to the ordering physician within fourteen calendar days after the sample and completed RT Voucher were received in the case of genotype-based RT and within three (3) calendar days in the case of the virtual phenotypic service. The turnaround time clock starts when the Contractor receives complete data and an adequate sample. An identical RT report containing the Client URN and the RT Voucher Number, but with other patient identifiers removed, shall be submitted to the VRDL at the same time.
- M. Viral resistance test reports must include, but are not limited to, the following information:
  - 1. A very concise summary of known mutations, their impact on antiretroviral therapy (ART), and limitations of resistance testing when applied to clinical care of patients.
  - 2. Present mutations or phenotypic sensitivity, by individual drug including all licensed antiretroviral agents and those available through expanded access programs in the United States. This information is updated periodically and can be located in the *International AIDS Society – USA "Update of the Drug Resistance Mutations in HIV-1"*.
  - 3. Clear and concise interpretations for physicians with limited knowledge and experience with HIV treatment and molecular diagnostic techniques.
  - 4. Referral to in-house and external sources for assistance with interpretation and treatment implications. This includes reference to the National HIV Telephone Consultation Service – Warmline.

**Exhibit A**  
**Scope of Work**

- N. The Contractor shall enter all data elements from RT Voucher into an appropriate computer-readable form specified by VRDL. For genotype-based RTs, the complete DNA sequence obtained starting at codon 1 of the HIV protease and continuing through codon 240 of the HIV reverse transcriptase gene shall also be submitted to VRDL in an appropriate electronic format. The Contractor shall transmit the data electronically via email to the VRDL within fourteen days after the sample and completed RT Voucher were received in the case of genotype-based RT and within 3 days for the virtual phenotypic service.
- O. The Contractor shall maintain Clinical Laboratory Improvements Amendments (CLIA) licensure, an ongoing RT quality assurance/quality control program, and participate in a periodic statewide proficiency-testing program, administered by the VRDL. The proficiency program will consist of testing a panel of 3 standardized samples up to 3 times per year (total of 9 sample tests). This testing will be performed and reimbursed by the same mechanism as all other RT tests.
- P. The Contractor shall also ensure that RT services described, submitted, and approved as a result of the request for proposal (RFA) #TMP 06-01 are adhered to.
- Q. Any additional RT-related tests authorized by OA and VRDL may be reimbursable under this contract. Prior written authorization by VRDL and OA is required before implementation of any other test. The appropriate cost for such testing will be negotiated prior to approval.

**6. Allowable Informal Scope of Work Changes**

- A. Changes and revisions to the Scope of Work contained in the agreement, utilizing the "**allowable cost payment system**", may be proposed by the Contractor in writing. All requested changes and revisions are subject to the approval of the State. Failure to notify the State of proposed revisions to the Scope of Work may result in an audit finding.
- B. The State will respond, in writing, as to the approval or disapproval of all such requests for changes or revisions to the Scope of Work within 30 calendar days of the date the request is received in the program. Should the State fail to respond to the Contractor's request within 30 calendar days of receipt, the Contractor's request shall be deemed approved.
- C. The State may also request changes and revisions to the Scope of Work. The State will make a good-faith effort to provide the Contractor 30 calendar days advance written notice of said changes or revisions.

**Exhibit B**  
**Budget Detail and Payment Provisions**

**1. Invoicing and Payment**

- A. For services satisfactorily rendered, and upon receipt and approval of the invoices, the State agrees to compensate the Contractor for actual expenditures incurred in accordance with the rates and/or allowable costs specified herein.
- B. Invoices shall include the Agreement Number and shall be submitted not more frequently than monthly in arrears to:

Attn: Invoice Desk  
California Department of Public Health  
Office of AIDS  
MS 7700  
P.O. Box 997426  
Sacramento, CA 95899-7426

C. Invoices shall:

- 1) Be prepared on Contractor letterhead. If invoices are not on produced letterhead invoices must be signed by an authorized official, employee or agent certifying that the expenditures claimed represent actual expenses for the service performed under this contract.
- 2) Bear the Contractor's name as shown on the agreement.
- 3) Identify the billing and/or performance period covered by the invoice.
- 4) Itemize costs for the billing period in the same or greater level of detail as indicated in this agreement. Subject to the terms of this agreement, reimbursement may only be sought for those costs and/or cost categories expressly identified as allowable in this agreement and approved by CDPH.

**D. Rates Payable**

Contractor will be reimbursed on a fee-for-services basis for services satisfactorily performed based on the following rate schedule:

- 1. \$360.00 for each genotype-based resistance test
- 2. \$145.00 for each virtual phenotype service

- E. The client's medical provider shall determine the type of test (e.g., genotype, phenotype, virtual phenotype), the laboratory they wish to conduct the resistance test, the number of tests per individual, and the frequency of testing. However, the EIP or LHJ may in response to local demand, establish a limit or guideline for the number of free, prepaid tests a client may receive each year through the TMP.
- F. The Contractor will not be reimbursed for tests performed on samples with an incomplete voucher or on samples received without a voucher. In addition, reimbursement will not occur for virtual phenotypic specimens that do not adhere to the criteria in Exhibit A, Scope of Work, Section E. Payment will be withheld if the data submitted is incomplete, invalid, or in a format not acceptable to the Department.
- G. The Contractor must invoice the State within 60 days of completed resistance testing service. The Contractor will be reimbursed for service after clean, verifiable, and timely data is received by VRDL.

**Exhibit B**  
**Budget Detail and Payment Provisions**

- H. A completed test is defined as one for which all laboratory processes required by the Department and the testing technology being used are completed successfully, a report of the applicable genetic sequence is provided to the ordering clinician, and a report of the applicable genetic sequence, voucher data, and frozen plasma are provided to VRDL in Richmond, CA.

**2. Budget Contingency Clause**

- A. It is mutually agreed that if the Budget Act of the current year and/or any subsequent years covered under this Agreement does not appropriate sufficient funds for the program, this Agreement shall be of no further force and effect. In this event, the State shall have no liability to pay any funds whatsoever to Contractor or to furnish any other considerations under this Agreement and Contractor shall not be obligated to perform any provisions of this Agreement.
- B. If funding for any fiscal year is reduced or deleted by the Budget Act for purposes of this program, the State shall have the option to either cancel this Agreement with no liability occurring to the State, or offer an agreement amendment to Contractor to reflect the reduced amount.

**3. Prompt Payment Clause**

Payment will be made in accordance with, and within the time specified in, Government Code Chapter 4.5, commencing with Section 927.

**4. Timely Submission of Final Invoice**

- A. A final undisputed invoice shall be submitted for payment no more than ninety (90) calendar days following the expiration or termination date of this agreement, unless a later or alternate deadline is agreed to in writing by the program contract manager. Said invoice should be clearly marked "Final Invoice", thus indicating that all payment obligations of the State under this agreement have ceased and that no further payments are due or outstanding.
- B. The State may, at its discretion, choose not to honor any delinquent final invoice if the Contractor fails to obtain prior written State approval of an alternate final invoice submission deadline. Written State approval shall be sought from the program contract manager prior to the expiration or termination date of this agreement.
- C. The Contractor is hereby advised of its obligation to submit, with the final invoice, a "**Contractor's Release (Exhibit F)**" acknowledging submission of the final invoice to the State and certifying the approximate percentage amount, if any, of recycled products used in performance of this agreement.

**5. Expense Allowability / Fiscal Documentation**

- A. Invoices, received from a Contractor and accepted and/or submitted for payment by the State, shall not be deemed evidence of allowable agreement costs.
- B. Contractor shall maintain for review and audit and supply to CDPH upon request, adequate documentation of all expenses claimed pursuant to this agreement to permit a determination of expense allowability.

**Exhibit B**  
**Budget Detail and Payment Provisions**

- C. If the allowability or appropriateness of an expense cannot be determined by the State because invoice detail, fiscal records, or backup documentation is nonexistent or inadequate according to generally accepted accounting principles or practices, all questionable costs may be disallowed and payment may be withheld by the State. Upon receipt of adequate documentation supporting a disallowed or questionable expense, reimbursement may resume for the amount substantiated and deemed allowable.
- D. Costs and/or expenses deemed unallowable are subject to recovery by CDPH. See provision 6 in this exhibit entitled, "Recovery of Overpayments" for more information.

**6. Recovery of Overpayments**

- A. Contractor agrees that claims based upon a contractual agreement or an audit finding and/or an audit finding that is appealed and upheld, will be recovered by the State by one of the following options:
  - 1) Contractor's remittance to the State of the full amount of the audit exception within 30 days following the State's request for repayment;
  - 2) A repayment schedule which is agreeable to both the State and the Contractor.
- B. The State reserves the right to select which option will be employed and the Contractor will be notified by the State in writing of the claim procedure to be utilized.
- C. Interest on the unpaid balance of the audit finding or debt will accrue at a rate equal to the monthly average of the rate received on investments in the Pooled Money Investment Fund commencing on the date that an audit or examination finding is mailed to the Contractor, beginning 30 days after Contractor's receipt of the State's demand for repayment.
- D. If the Contractor has filed a valid appeal regarding the report of audit findings, recovery of the overpayments will be deferred until a final administrative decision on the appeal has been reached. If the Contractor loses the final administrative appeal, Contractor shall repay, to the State, the over-claimed or disallowed expenses, plus accrued interest. Interest accrues from the Contractor's first receipt of State's notice requesting reimbursement of questioned audit costs or disallowed expenses.



**Exhibit B  
Attachment I**

SAMPLE INVOICE FORMAT

**HIV-1 RESISTANCE TEST SERVICES  
HIV THERAPEUTIC MONITORING PROGRAM  
CALIFORNIA DEPARTMENT OF PUBLIC HEALTH, OFFICE OF AIDS**

**Contractor:**

Contractor Name  
Street Address  
City, State ZIP

Contract Number 07-xxxxx

Contract Term: July 1, 2007 to June 30, 2010

Expense Period: December 2007

**Bill To:**

California Dept. of Public Health  
Office of AIDS  
ATTN: Toni M. Post  
MS 7700  
P.O. Box 997426  
Sacramento, CA 95899-7426

**Total Due for this Invoice: \$1,225**

Check applicable box(es):

<input type="checkbox"/>	Genotype @ \$360 per completed test Total Genotypes: 3	Amount Payable:	\$1,080
<input type="checkbox"/>	Phenotype @ \$675 per completed test Total Phenotypes: 0	Amount Payable:	\$ 0
<input type="checkbox"/>	Virtual Phenotype @ \$145 per completed test Total Virtual Phenotypes: 1	Amount Payable:	\$ 145
TOTAL DUE:			<u>\$1,225</u>

SIGNATURE: \_\_\_\_\_

\*\*\*\*\*

No.	Client URN	Voucher No.	Date of Service	Type of Test
1	KUNP1109722	G0000101	12/03/07	Genotype
2	ENVD0805652	G0000103	12/10/07	Genotype
3	RBSM0457411	G0000102	12/13/07	Genotype
4	RBSM0457411	VP0000001	12/27/07	Virtual Phenotype

**FOR USE IN FY 2007/2008 ONLY**  
**GENOTYPIC HIV-1 RESISTANCE TEST VOUCHER**

*Complete fully and submit with each resistance test sample.*

<b>SELECT ONE LAB FOR GENOTYPIC TESTING:</b>  <input type="checkbox"/> Advanced Medical Analysis <input type="checkbox"/> Los Angeles County Public Health Laboratory <input type="checkbox"/> Monogram Biosciences <input type="checkbox"/> San Bernardino County Public Health Laboratory <input type="checkbox"/> Siemens Medical Solutions <input type="checkbox"/> UCSF/ARI Laboratory of Clinical Virology  <b>NAME OF AUTHORIZED LOCATION</b>  Address (number, street)  <table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 50%;">Authorized Location Number (4 digits)</td><td style="width: 50%;">Telephone Number</td></tr></table> Submitting Physician Name  Physician E-mail Address (optional)  <b>DATE OF BIRTH</b> (mm/dd/yyyy)  <b>GENDER</b> (select only one)  <input type="checkbox"/> (1) Male <input type="checkbox"/> (3) Transgender (Male to Female) <input type="checkbox"/> (2) Female <input type="checkbox"/> (4) Transgender (Female to Male) <input type="checkbox"/> (9) Unknown  <b>ZIP CODE OF PRIMARY RESIDENCE</b>  <input type="checkbox"/> (99999) Unknown <input type="checkbox"/> (99997) Homeless  <b>INDIVIDUAL ANNUAL FEDERAL ADJUSTED GROSS INCOME</b>  (Must Be Below \$50,000) \$  <b>ETHNICITY</b> (select only one)  <input type="checkbox"/> (100) White (non-Hispanic) <input type="checkbox"/> (200) Black (non-Hispanic), African-American <input type="checkbox"/> (300) Hispanic <input type="checkbox"/> (400) Asian, Pacific Islander <input type="checkbox"/> (500) Native American/Alaskan <input type="checkbox"/> (600) Other <input type="checkbox"/> (999) Unknown	Authorized Location Number (4 digits)	Telephone Number	<b>*CLIENT NAME</b> (last, first, mi)  *Contracting lab. You must remove name before sending voucher data to VRDL. <b>CLIENT MEDICAL RECORD NUMBER</b> (optional)  <table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 50%;">Most recent CD4 count</td><td style="width: 50%;">Date</td></tr></table> <table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 50%;">Most recent viral load</td><td style="width: 50%;">Date</td></tr></table> <b>STATE EIP CLIENT NUMBER</b> (11 digits) (Required for All state-funded Early Intervention Program clients)  <b>Client Unique Record Number (URN) - Required for ALL clients</b> (See back to compose unencrypted 11 characters)  <b>RT SPECIMEN</b> <table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 50%;">Date blood collected (mm/dd/yyyy)</td><td style="width: 50%;">Time blood collected</td></tr></table> <table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 50%;">Date plasma frozen (mm/dd/yyyy)</td><td style="width: 50%;">Time plasma frozen</td></tr></table> Sample prepared and shipped according to laboratory requirements? <input type="checkbox"/> Yes <input type="checkbox"/> No  <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"><b>FOR LABORATORY USE ONLY</b> Laboratory accession number <table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 50%;">Date specimen was received</td><td style="width: 50%;">Time specimen was received</td></tr></table> <table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 50%;">Date report sent to clinician</td><td style="width: 50%;">Date results forwarded to VRDL</td></tr></table> Microbiologist/technologist initials</div> Voucher Number: _____	Most recent CD4 count	Date	Most recent viral load	Date	Date blood collected (mm/dd/yyyy)	Time blood collected	Date plasma frozen (mm/dd/yyyy)	Time plasma frozen	Date specimen was received	Time specimen was received	Date report sent to clinician	Date results forwarded to VRDL
Authorized Location Number (4 digits)	Telephone Number														
Most recent CD4 count	Date														
Most recent viral load	Date														
Date blood collected (mm/dd/yyyy)	Time blood collected														
Date plasma frozen (mm/dd/yyyy)	Time plasma frozen														
Date specimen was received	Time specimen was received														
Date report sent to clinician	Date results forwarded to VRDL														

Exhibit B  
Attachment II

**CLIENT UNIQUE RECORD NUMBER (URN)—Unencrypted**

Consists of eleven capital letters and numbers composed as follows:

Character	Description
1	First letter of legal <b>*first name</b> ; if unavailable, use digit 9
2	Third letter of legal <b>*first name</b> ; if unavailable, use middle initial; if no middle initial, use digit 9
3	First letter of legal <b>*last name</b> ; if unavailable, use digit 9
4	Third letter of legal <b>*last name</b> ; if unavailable, use digit 9
5-6	Month of birth as two digits
7-8	Day of birth as two digits
9-10	Year of birth as two digits; if date of birth not available, use 999999 for characters 5-10
11	One digit gender code (1=Male, 2=Female, 3 or 4=Transgender, 9=Unknown)

*\*No aliases or nicknames allowed.*

**FOR USE IN FY 2007/2008 ONLY**  
**VIRTUAL PHENOTYPIC SERVICE VOUCHER**

**SELECT ONE LAB FOR VIRTUAL PHENOTYPING SERVICE:\***

- ☐ Advanced Medical Analysis  
☐ Los Angeles County Public Health Laboratory  
☐ UCSF/ARI Laboratory of Clinical Virology

**\* NOTE: Service to be conducted on a genotype that was performed by this laboratory within the past 30 days. Please see back for additional important information.**

**NAME OF AUTHORIZED LOCATION**

Address (number, street)

Authorized Location Number  
(4 digits) \_\_\_\_\_

Telephone Number

Submitting Physician Name

Physician E-mail Address (optional)

**INDIVIDUAL ANNUAL FEDERAL ADJUSTED GROSS INCOME**

(Must Be Below \$50,000) \$ \_\_\_\_\_

**ZIP CODE OF PRIMARY RESIDENCE**

\_\_\_\_\_

- ☐ (99999) Unknown  
☐ (99997) Homeless

**ETHNICITY (select only one)**

- ☐ (100) White (non-Hispanic)  
☐ (200) Black (non-Hispanic), African-American  
☐ (300) Hispanic  
☐ (400) Asian, Pacific Islander  
☐ (500) Native American/Alaskan  
☐ (600) Other  
☐ (999) Unknown

**\*CLIENT NAME** (last, first, mi)

\*Contracting lab. You must remove name before sending voucher data to VRDL.

**CLIENT MEDICAL RECORD NUMBER (optional)**

Most recent CD4 count

Date

\_\_\_\_/\_\_\_\_/\_\_\_\_

Most recent viral load

Date

\_\_\_\_/\_\_\_\_/\_\_\_\_

**STATE EIP CLIENT NUMBER (11 digits)**

(Required for All state-funded Early Intervention Program clients)

**DATE OF BIRTH** (mm/dd/yyyy)

\_\_\_\_/\_\_\_\_/\_\_\_\_

**GENDER (select only one)**

- ☐ (1) Male ☐ (3) Transgender (Male to Female)  
☐ (2) Female ☐ (4) Transgender (Female to Male)  
☐ (9) Unknown

**Client Unique Record Number (URN) - Required for ALL clients**  
(See back to compose unencrypted 11 characters)

\_\_\_\_/\_\_\_\_/\_\_\_\_/\_\_\_\_/\_\_\_\_/\_\_\_\_

Voucher Number: \_\_\_\_\_

Exhibit B  
Attachment III

**ADDITIONAL IMPORTANT INFORMATION:**

All data fields are required except for client's medical record number and physician email address.

GENOTYPIC testing ONLY is the preferred approach for resistance testing. However, based on the results of a recent genotypic test (within 30 days), a clinician may want to consider ordering a virtual phenotype. If so, please adhere to the following guidelines:

**VIRTUAL PHENOTYPE**

A virtual phenotype **should not** be ordered on an ARV-naïve patient unless there is evidence of drug resistance. In addition, a virtual phenotype **should not** be performed if the genotype shows:

- a) Susceptibility (no evidence of resistance or possible resistance) to all drug classes
- b) The M184V mutation conferring lamivudine (3TC) resistance only
- c) Any nonnucleoside (NNRTI) mutation in the absence of resistance to other drug classes
- d) The D30N mutation conferring nelfinavir (NFV) resistance only
- e) Protease inhibitor polymorphisms or mutations that are not associated with resistance or possible resistance
- f) Any combination of b, c, d, and e

**CLIENT UNIQUE RECORD NUMBER (URN)—Unencrypted**

Consists of eleven capital letters and numbers composed as follows:

Character	Description
1	First letter of legal <b>*first name</b> ; if unavailable, use digit 9
2	Third letter of legal <b>*first name</b> ; if unavailable, use middle initial; if no middle initial, use digit 9
3	First letter of legal <b>*last name</b> ; if unavailable, use digit 9
4	Third letter of legal <b>*last name</b> ; if unavailable, use digit 9
5–6	Month of birth as two digits
7–8	Day of birth as two digits
9–10	Year of birth as two digits; if date of birth not available, use 999999 for characters 5–10
11	One digit gender code (1=Male, 2=Female, 3 or 4=Transgender, 9=Unknown)

*\*No aliases or nicknames allowed.*

### Special Terms and Conditions

*(For State funded subvention, local assistance and direct service contracts and grant agreements)*

The use of headings or titles throughout this exhibit is for convenience only and shall not be used to interpret or govern the meaning of any specific term or condition. The terms "contract", "Contractor" and "Subcontractor" shall also mean, "grant", "Grantee" and "Subgrantee" respectively.

This exhibit contains provisions that require strict adherence to various contracting laws and policies. Some provisions herein are conditional and only apply if specified conditions exist (i.e., agreement total exceeds a certain amount, agreement is federally funded, etc.). The provisions herein apply to this agreement unless the provisions are removed by reference on the face of the agreement, the provisions are superseded by an alternate provision appearing elsewhere in the agreement, or the applicable conditions do not exist.

### Index of Special Terms and Conditions

1. Travel and Per Diem Reimbursement
2. Procurement Rules
3. Equipment Ownership / Inventory / Disposition
4. Subcontract Requirements
5. Income Restrictions
6. Audit and Record Retention
7. Site Inspection
8. Intellectual Property Rights
9. Prior Approval of Training Seminars, Workshops, or Conferences
10. Confidentiality of Information
11. Documents, Publications and Written Reports
12. Dispute Resolution Process
13. Financial and Compliance Audit Requirements
14. Novation Requirements
15. Payment Withholds
16. Performance Evaluation
17. Officials Not to Benefit
18. Four-Digit Date Compliance
19. Union Organizing
20. Contract Uniformity (Fringe Benefit Allowability)

## 1. Travel and Per Diem Reimbursement

(Applicable if travel and/or per diem expenses are reimbursed with contract funds.)

Reimbursement for travel and per diem expenses from the California Department of Public Health (CDPH) under this agreement shall, unless otherwise specified in this agreement, be at the rates currently in effect, as established by the California Department of Personnel Administration (DPA), for nonrepresented state employees as stipulated in CDPH's Travel Reimbursement Information Exhibit. If the DPA rates change during the term of the agreement, the new rates shall apply upon their effective date and no amendment to this agreement shall be necessary. Exceptions to DPA rates may be approved by CDPH upon the submission of a statement by the Contractor indicating that such rates are not available to the Contractor. No travel outside the State of California shall be reimbursed without prior authorization from CDPH. Verbal authorization should be confirmed in writing. Written authorization may be in a form including fax or email confirmation.

## 2. Procurement Rules

(Applicable to all agreements in which equipment, miscellaneous property, commodities and/or supplies are furnished by CDPH or expenses for said items are reimbursed with state funds.)

### a. Equipment definitions

Wherever the term equipment and/or miscellaneous property is used, the following definitions shall apply:

- (1) **Major equipment:** A tangible or intangible item having a base unit cost of \$5,000 or more with a life expectancy of one (1) year or more and is either furnished by CDPH or the cost is reimbursed through this agreement. Software and videos are examples of intangible items that meet this definition.
- (2) **Minor equipment:** A tangible item having a base unit cost of less than \$5,000 with a life expectancy of one (1) year or more that is listed on the CDPH Asset Management Unit's Minor Equipment List and is either furnished by CDPH or the cost is reimbursed through this agreement. Contractors may obtain a copy of the Minor Equipment List by making a request through the CDPH program contract manager.
- (3) **Miscellaneous property:** A specific tangible item with a life expectancy of one (1) year or more that is either furnished by CDPH or the cost is reimbursed through this agreement. Examples include, but are not limited to: furniture (excluding modular furniture), cabinets, typewriters, desktop calculators, portable dictators, non-digital cameras, etc.

- b. **Government and public entities** (including state colleges/universities and auxiliary organizations), whether acting as a contractor and/or subcontractor, may secure all commodities, supplies, equipment and services related to such purchases that are required in performance of this agreement. Said procurements are subject to Paragraphs d through h of Provision 2. Paragraph c of Provision 2 shall also apply, if equipment purchases are delegated to subcontractors that are nonprofit organizations or commercial businesses.

- c. **Nonprofit organizations and commercial businesses**, whether acting as a contractor and/or subcontractor, may secure commodities, supplies, equipment and services related to such purchases for performance under this agreement.

- (1) Equipment purchases shall not exceed \$50,000 annually.

To secure equipment above the annual maximum limit of \$50,000, the Contractor shall make arrangements through the appropriate CDPH program contract manager, to have all remaining equipment purchased through CDPH's Purchasing Unit. The cost of equipment purchased by or through CDPH shall be deducted from the funds available in this agreement. Contractor shall submit to the CDPH program contract manager a list of equipment specifications for those items that the State must procure. The State may pay the vendor

directly for such arranged equipment purchases and title to the equipment will remain with CDPH. The equipment will be delivered to the Contractor's address, as stated on the face of the agreement, unless the Contractor notifies the CDPH program contract manager, in writing, of an alternate delivery address.

- (2) All equipment purchases are subject to Paragraphs d through h of Provision 2. Paragraph b of Provision 2 shall also apply, if equipment purchases are delegated to subcontractors that are either a government or public entity.
- (3) Nonprofit organizations and commercial businesses, shall use a procurement system that meets the following standards:
  - (a) Maintain a code or standard of conduct that shall govern the performance of its officers, employees, or agents engaged in awarding procurement contracts. No employee, officer, or agent shall participate in the selection, award, or administration of a procurement contract in which, to his or her knowledge, he or she has a financial interest.
  - (b) Procurements shall be conducted in a manner that provides, to the maximum extent practical, open, and free competition.
  - (c) Procurements shall be conducted in a manner that provides for all of the following:
    - [1] Avoid purchasing unnecessary or duplicate items.
    - [2] Equipment solicitations shall be based upon a clear and accurate description of the technical requirements of the goods to be procured.
    - [3] Take positive steps to utilize small and veteran owned businesses.
- d. Unless waived or otherwise stipulated in writing by CDPH, prior written authorization from the appropriate CDPH program contract manager will be required before the Contractor will be reimbursed for any purchase of \$5,000 or more for commodities, supplies, equipment, and services related to such purchases. The Contractor must provide in its request for authorization all particulars necessary, as specified by CDPH, for evaluating the necessity or desirability of incurring such costs. The term "purchase" excludes the purchase of services from a subcontractor and public utility services at rates established for uniform applicability to the general public.
- e. In special circumstances, determined by CDPH (e.g., when CDPH has a need to monitor certain purchases, etc.), CDPH may require prior written authorization and/or the submission of paid vendor receipts for any purchase, regardless of dollar amount. CDPH reserves the right to either deny claims for reimbursement or to request repayment for any Contractor and/or subcontractor purchase that CDPH determines to be unnecessary in carrying out performance under this agreement.
- f. The Contractor and/or subcontractor must maintain a copy or narrative description of the procurement system, guidelines, rules, or regulations that will be used to make purchases under this agreement. The State reserves the right to request a copy of these documents and to inspect the purchasing practices of the Contractor and/or subcontractor at any time.
- g. For all purchases, the Contractor and/or subcontractor must maintain copies of all paid vendor invoices, documents, bids and other information used in vendor selection, for inspection or audit. Justifications supporting the absence of bidding (i.e., sole source purchases) shall also be maintained on file by the Contractor and/or subcontractor for inspection or audit.
- h. CDPH may, with cause (e.g., with reasonable suspicion of unnecessary purchases or use of inappropriate purchase practices, etc.), withhold, cancel, modify, or retract the delegated purchase authority granted under Paragraphs b and/or c of Provision 2 by giving the Contractor no less than 30 calendar days written notice.



**3. Equipment Ownership / Inventory / Disposition**

(Applicable to agreements in which equipment and/or miscellaneous property is furnished by CDPH and/or when said items are purchased or reimbursed with state funds.)

- a. Wherever the term equipment and/or miscellaneous property is used in Provision 3, the definitions in Provision 2, Paragraph a shall apply.

Unless otherwise stipulated in this agreement, all equipment and/or miscellaneous property that are purchased/reimbursed with agreement funds or furnished by CDPH under the terms of this agreement shall be considered state equipment and the property of CDPH.

- (1) CDPH requires the reporting, tagging and annual inventorying of all equipment and/or miscellaneous property that is furnished by CDPH or purchased/reimbursed with funds provided through this agreement.

Upon receipt of equipment and/or miscellaneous property, the Contractor shall report the receipt to the CDPH program contract manager. To report the receipt of said items and to receive property tags, the Contractor shall use a form or format designated by CDPH's Asset Management Unit. If the appropriate form (i.e., Contractor Equipment Purchased with CDPH Funds) does not accompany this agreement, Contractor shall request a copy from the CDPH program contract manager.

- (2) If the Contractor enters into an agreement with a term of more than twelve months, the Contractor shall submit an annual inventory of state equipment and/or miscellaneous property to the CDPH program contract manager using a form or format designated by CDPH's Asset Management Unit. If an inventory report form (i.e., Inventory/Disposition of CDPH-Funded Equipment) does not accompany this agreement, Contractor shall request a copy from the CDPH program contract manager. Contractor shall:

- (a) Include in the inventory report, equipment and/or miscellaneous property in the Contractor's possession and/or in the possession of a subcontractor (including independent consultants).

- (b) Submit the inventory report to CDPH according to the instructions appearing on the form or issued by the CDPH program contract manager.

- (c) Contact the CDPH program contract manager to learn how to remove, trade-in, sell, transfer or survey off, from the inventory report, expired equipment and/or miscellaneous property that is no longer wanted, usable or has passed its life expectancy. Instructions will be supplied by CDPH's Asset Management Unit.

- b. Title to state equipment and/or miscellaneous property shall not be affected by its incorporation or attachment to any property not owned by the State.

- c. Unless otherwise stipulated, CDPH shall be under no obligation to pay the cost of restoration, or rehabilitation of the Contractor's and/or Subcontractor's facility which may be affected by the removal of any state equipment and/or miscellaneous property.

- d. The Contractor and/or Subcontractor shall maintain and administer a sound business program for ensuring the proper use, maintenance, repair, protection, insurance and preservation of state equipment and/or miscellaneous property.

- (1) In administering this provision, CDPH may require the Contractor and/or Subcontractor to repair or replace, to CDPH's satisfaction, any damaged, lost or stolen state equipment and/or miscellaneous property. In the event of state equipment and/or miscellaneous property theft, Contractor and/or Subcontractor shall immediately file a theft report with the appropriate police agency or the California Highway Patrol and Contractor shall promptly submit one copy of the theft report to the CDPH program contract manager.

- e. Unless otherwise stipulated by the program funding this agreement, equipment and/or miscellaneous property purchased/reimbursed with agreement funds or furnished by CDPH under the terms of this agreement, shall only be used for performance of this agreement or another CDPH agreement.
- f. Within sixty (60) calendar days prior to the termination or end of this agreement, the Contractor shall provide a final inventory report of equipment and/or miscellaneous property to the CDPH program contract manager and shall, at that time, query CDPH as to the requirements, including the manner and method, of returning state equipment and/or miscellaneous property to CDPH. Final disposition of equipment and/or miscellaneous property shall be at CDPH expense and according to CDPH instructions. Equipment and/or miscellaneous property disposition instructions shall be issued by CDPH immediately after receipt of the final inventory report. At the termination or conclusion of this agreement, CDPH may at its discretion, authorize the continued use of state equipment and/or miscellaneous property for performance of work under a different CDPH agreement.

**g. Motor Vehicles**

(Applicable only if motor vehicles are purchased/reimbursed with agreement funds or furnished by CDPH under this agreement.)

- (1) If motor vehicles are purchased/reimbursed with agreement funds or furnished by CDPH under the terms of this agreement, within thirty (30) calendar days prior to the termination or end of this agreement, the Contractor and/or Subcontractor shall return such vehicles to CDPH and shall deliver all necessary documents of title or registration to enable the proper transfer of a marketable title to CDPH.
- (2) If motor vehicles are purchased/reimbursed with agreement funds or furnished by CDPH under the terms of this agreement, the State of California shall be the legal owner of said motor vehicles and the Contractor shall be the registered owner. The Contractor and/or a subcontractor may only use said vehicles for performance and under the terms of this agreement.
- (3) The Contractor and/or Subcontractor agree that all operators of motor vehicles, purchased/reimbursed with agreement funds or furnished by CDPH under the terms of this agreement, shall hold a valid State of California driver's license. In the event that ten or more passengers are to be transported in any one vehicle, the operator shall also hold a State of California Class B driver's license.
- (4) If any motor vehicle is purchased/reimbursed with agreement funds or furnished by CDPH under the terms of this agreement, the Contractor and/or Subcontractor, as applicable, shall provide, maintain, and certify that, at a minimum, the following type and amount of automobile liability insurance is in effect during the term of this agreement or any period of contract extension during which any vehicle remains in the Contractor's and/or Subcontractor's possession:

**Automobile Liability Insurance**

- (a) The Contractor, by signing this agreement, hereby certifies that it possesses or will obtain automobile liability insurance in the amount of \$1,000,000 per occurrence for bodily injury and property damage combined. Said insurance must be obtained and made effective upon the delivery date of any motor vehicle, purchased/reimbursed with agreement funds or furnished by CDPH under the terms of this agreement, to the Contractor and/or Subcontractor.
- (b) The Contractor and/or Subcontractor shall, as soon as practical, furnish a copy of the certificate of insurance to the CDPH program contract manager.

- (c) The Contractor and/or Subcontractor agree that bodily injury and property damage liability insurance, as required herein, shall remain in effect at all times during the term of this agreement or until such time as the motor vehicle is returned to CDPH.
- (d) The Contractor and/or Subcontractor agree to provide, at least thirty (30) days prior to the expiration date of said insurance coverage, a copy of a new certificate of insurance evidencing continued coverage, as indicated herein, for not less than the remainder of the term of this agreement, the term of any extension or continuation thereof, or for a period of not less than one (1) year.
- (e) The Contractor and/or Subcontractor, if not a self-insured government and/or public entity, must provide evidence, that any required certificates of insurance contain the following provisions:
  - [1] The insurer will not cancel the insured's coverage without giving thirty (30) calendar days prior written notice to the State (California Department of Public Health).
  - [2] The State of California, its officers, agents, employees, and servants are included as additional insureds, but only with respect to work performed for the State under this agreement and any extension or continuation of this agreement.
  - [3] The insurance carrier shall notify the California Department of Public Health, in writing, of the Contractor's failure to pay premiums; its cancellation of such policies; or any other substantial change, including, but not limited to, the status, coverage, or scope of the required insurance. Such notices shall contain a reference to the agreement number for which the insurance was obtained.
- (f) The Contractor and/or Subcontractor is hereby advised that copies of certificates of insurance may be subject to review and approval by the Department of General Services (DGS), Office of Risk and Insurance Management. The Contractor shall be notified by CDPH, in writing, if this provision is applicable to this agreement. If DGS approval of the certificate of insurance is required, the Contractor agrees that no work or services shall be performed prior to obtaining said approval.
- (g) In the event the Contractor and/or Subcontractor fails to keep insurance coverage, as required herein, in effect at all times during vehicle possession, CDPH may, in addition to any other remedies it may have, terminate this agreement upon the occurrence of such event.

#### 4. Subcontract Requirements

(Applicable to agreements under which services are to be performed by subcontractors including independent consultants.)

- a. Prior written authorization will be required before the Contractor enters into or is reimbursed for any subcontract for services costing \$5,000 or more. Except as indicated in Paragraph a(3) herein, when securing subcontracts for services exceeding \$5,000, the Contractor shall obtain at least three bids or justify a sole source award.
  - (1) The Contractor must provide in its request for authorization, all information necessary for evaluating the necessity or desirability of incurring such cost.
  - (2) The State may identify the information needed to fulfill this requirement.
  - (3) Subcontracts performed by the following entities or for the service types listed below are exempt from the bidding and sole source justification requirements:
    - (a) A local governmental entity or the federal government,
    - (b) A State college or university from any State,
    - (c) A Joint Powers Authority,

- (d) An auxiliary organization of a California State University or a California community college,
  - (e) A foundation organized to support the Board of Governors of the California Community Colleges,
  - (f) An auxiliary organization of the Student Aid Commission established under Education Code § 69522,
  - (g) Entities of any type that will provide subvention aid or direct services to the public,
  - (h) Entities and/or service types identified as exempt from advertising in State Administrative Manual Section 1233 subsection 3. View this publication at the following Internet address: <http://sam.dgs.ca.gov>.
- b. CDPH reserves the right to approve or disapprove the selection of subcontractors and with advance written notice, require the substitution of subcontractors and require the Contractor to terminate subcontracts entered into in support of this agreement.
- (1) Upon receipt of a written notice from CDPH requiring the substitution and/or termination of a subcontract, the Contractor shall take steps to ensure the completion of any work in progress and select a replacement, if applicable, within 30 calendar days, unless a longer period is agreed to by CDPH.
- c. Actual subcontracts (i.e., written agreement between the Contractor and a subcontractor) of \$5,000 or more are subject to the prior review and written approval of CDPH. CDPH may, at its discretion, elect to waive this right. All such waivers shall be confirmed in writing by CDPH.
- d. Contractor shall maintain a copy of each subcontract entered into in support of this agreement and shall, upon request by CDPH, make copies available for approval, inspection, or audit.
- e. CDPH assumes no responsibility for the payment of subcontractors used in the performance of the agreement. Contractor accepts sole responsibility for the payment of subcontractors used in the performance of this agreement.
- f. The Contractor is responsible for all performance requirements under this agreement even though performance may be carried out through a subcontract.
- g. The Contractor shall ensure that all subcontracts for services include provision(s) requiring compliance with applicable terms and conditions specified in this agreement.
- h. The Contractor agrees to include the following clause, relevant to record retention, in all subcontracts for services:
- "(Subcontractor Name) agrees to maintain and preserve, until three years after termination of (Agreement Number) and final payment from CDPH to the Contractor, to permit CDPH or any duly authorized representative, to have access to, examine or audit any pertinent books, documents, papers and records related to this subcontract and to allow interviews of any employees who might reasonably have information related to such records."
- i. Unless otherwise stipulated in writing by CDPH, the Contractor shall be the subcontractor's sole point of contact for all matters related to performance and payment under this agreement.
- j. Contractor shall, as applicable, advise all subcontractors of their obligations pursuant to the following numbered provisions of this Exhibit: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, and 17.

## 5. Income Restrictions

Unless otherwise stipulated in this agreement, the Contractor agrees that any refunds, rebates, credits, or other amounts (including any interest thereon) accruing to or received by the Contractor under this agreement shall be paid by the Contractor to CDPH, to the extent that they are properly allocable to costs for which the Contractor has been reimbursed by CDPH under this agreement.

**6. Audit and Record Retention**

(Applicable to agreements over \$10,000.)

- a. The Contractor and/or Subcontractor shall maintain books, records, documents, and other evidence, accounting procedures, and practices, sufficient to properly reflect all direct and indirect costs of whatever nature claimed to have been incurred in the performance of this agreement, including any matching costs and expenses. The foregoing constitutes "records" for the purposes of this provision.
- b. The Contractor's and/or Subcontractor's facility or office or such part thereof as may be engaged in the performance of this agreement and his/her records shall be subject at all reasonable times to inspection, audit, and reproduction.
- c. Contractor agrees that CDPH, the Department of General Services, the Bureau of State Audits, or their designated representatives shall have the right to review and to copy any records and supporting documentation pertaining to the performance of this agreement. Contractor agrees to allow the auditor(s) access to such records during normal business hours and to allow interviews of any employees who might reasonably have information related to such records. Further, the Contractor agrees to include a similar right of the State to audit records and interview staff in any subcontract related to performance of this agreement. (GC 8546.7, CCR Title 2, Section 1896).
- d. The Contractor and/or Subcontractor shall preserve and make available his/her records (1) for a period of three years from the date of final payment under this agreement, and (2) for such longer period, if any, as is required by applicable statute, by any other provision of this agreement, or by subparagraphs (1) or (2) below.
  - (1) If this agreement is completely or partially terminated, the records relating to the work terminated shall be preserved and made available for a period of three years from the date of any resulting final settlement.
  - (2) If any litigation, claim, negotiation, audit, or other action involving the records has been started before the expiration of the three-year period, the records shall be retained until completion of the action and resolution of all issues which arise from it, or until the end of the regular three-year period, whichever is later.
- e. The Contractor and/or Subcontractor shall comply with the above requirements and be aware of the penalties for violations of fraud and for obstruction of investigation as set forth in Public Contract Code § 10115.10, if applicable.
- f. The Contractor and/or Subcontractor may, at its discretion, following receipt of final payment under this agreement, reduce its accounts, books and records related to this agreement to microfilm, computer disk, CD ROM, or other data storage medium. Upon request by an authorized representative to inspect, audit or obtain copies of said records, the Contractor and/or subcontractor must supply or make available applicable devices, hardware, and/or software necessary to view, copy and/or print said records. Applicable devices may include, but are not limited to, microfilm readers and microfilm printers, etc.

**7. Site Inspection**

The State, through any authorized representatives, has the right at all reasonable times to inspect or otherwise evaluate the work performed or being performed hereunder including subcontract supported activities and the premises in which it is being performed. If any inspection or evaluation is made of the premises of the Contractor or Subcontractor, the Contractor shall provide and shall require Subcontractors to provide all reasonable facilities and assistance for the safety and convenience of the authorized representatives in the performance of their duties. All inspections and evaluations shall be performed in such a manner as will not unduly delay the work.

## 8. Intellectual Property Rights

### a. Ownership

- (1) Except where CDPH has agreed in a signed writing to accept a license, CDPH shall be and remain, without additional compensation, the sole owner of any and all rights, title and interest in all Intellectual Property, from the moment of creation, whether or not jointly conceived, that are made, conceived, derived from, or reduced to practice by Contractor or CDPH and which result directly or indirectly from this agreement.
- (2) For the purposes of this agreement, Intellectual Property means recognized protectable rights and interest such as: patents, (whether or not issued) copyrights, trademarks, service marks, applications for any of the foregoing, inventions, trade secrets, trade dress, logos, insignia, color combinations, slogans, moral rights, right of publicity, author's rights, contract and licensing rights, works, mask works, industrial design rights, rights of priority, know how, design flows, methodologies, devices, business processes, developments, innovations, good will and all other legal rights protecting intangible proprietary information as may exist now and/or here after come into existence, and all renewals and extensions, regardless of whether those rights arise under the laws of the United States, or any other state, country or jurisdiction.
  - (a) For the purposes of the definition of Intellectual Property, "works" means all literary works, writings and printed matter including the medium by which they are recorded or reproduced, photographs, art work, pictorial and graphic representations and works of a similar nature, film, motion pictures, digital images, animation cells, and other audiovisual works including positives and negatives thereof, sound recordings, tapes, educational materials, interactive videos and any other materials or products created, produced, conceptualized and fixed in a tangible medium of expression. It includes preliminary and final products and any materials and information developed for the purposes of producing those final products. Works does not include articles submitted to peer review or reference journals or independent research projects.
- (3) In the performance of this agreement, Contractor will exercise and utilize certain of its Intellectual Property in existence prior to the effective date of this agreement. In addition, under this agreement, Contractor may access and utilize certain of CDPH's Intellectual Property in existence prior to the effective date of this agreement. Except as otherwise set forth herein, Contractor shall not use any of CDPH's Intellectual Property now existing or hereafter existing for any purposes without the prior written permission of CDPH. **Except as otherwise set forth herein, neither the Contractor nor CDPH shall give any ownership interest in or rights to its Intellectual Property to the other Party.** If during the term of this agreement, Contractor accesses any third-party Intellectual Property that is licensed to CDPH, Contractor agrees to abide by all license and confidentiality restrictions applicable to CDPH in the third-party's license agreement.
- (4) Contractor agrees to cooperate with CDPH in establishing or maintaining CDPH's exclusive rights in the Intellectual Property, and in assuring CDPH's sole rights against third parties with respect to the Intellectual Property. If the Contractor enters into any agreements or subcontracts with other parties in order to perform this agreement, Contractor shall require the terms of the agreement(s) to include all Intellectual Property provisions. Such terms must include, but are not limited to, the subcontractor assigning and agreeing to assign to CDPH all rights, title and interest in Intellectual Property made, conceived, derived from, or reduced to practice by the subcontractor, Contractor or CDPH and which result directly or indirectly from this agreement or any subcontract.
- (5) Contractor further agrees to assist and cooperate with CDPH in all reasonable respects, and execute all documents and, subject to reasonable availability, give testimony and take all further acts reasonably necessary to acquire, transfer, maintain, and enforce CDPH's Intellectual Property rights and interests.

**b. Retained Rights / License Rights**

- (1) Except for Intellectual Property made, conceived, derived from, or reduced to practice by Contractor or CDPH and which result directly or indirectly from this agreement, Contractor shall retain title to all of its Intellectual Property to the extent such Intellectual Property is in existence prior to the effective date of this agreement. Contractor hereby grants to CDPH, without additional compensation, a permanent, non-exclusive, royalty free, paid-up, worldwide, irrevocable, perpetual, non-terminable license to use, reproduce, manufacture, sell, offer to sell, import, export, modify, publicly and privately display/perform, distribute, and dispose Contractor's Intellectual Property with the right to sublicense through multiple layers, for any purpose whatsoever, to the extent it is incorporated in the Intellectual Property resulting from this agreement, unless Contractor assigns all rights, title and interest in the Intellectual Property as set forth herein.
- (2) Nothing in this provision shall restrict, limit, or otherwise prevent Contractor from using any ideas, concepts, know-how, methodology or techniques related to its performance under this agreement, provided that Contractor's use does not infringe the patent, copyright, trademark rights, license or other Intellectual Property rights of CDPH or third party, or result in a breach or default of any provisions of this Exhibit or result in a breach of any provisions of law relating to confidentiality.

**c. Copyright**

- (1) Contractor agrees that for purposes of copyright law, all works [as defined in Section a, subparagraph (2)(a) of this provision] of authorship made by or on behalf of Contractor in connection with Contractor's performance of this agreement shall be deemed "works made for hire". Contractor further agrees that the work of each person utilized by Contractor in connection with the performance of this agreement will be a "work made for hire," whether that person is an employee of Contractor or that person has entered into an agreement with Contractor to perform the work. Contractor shall enter into a written agreement with any such person that: (i) all work performed for Contractor shall be deemed a "work made for hire" under the Copyright Act and (ii) that person shall assign all right, title, and interest to CDPH to any work product made, conceived, derived from, or reduced to practice by Contractor or CDPH and which result directly or indirectly from this agreement.
- (2) All materials, including, but not limited to, visual works or text, reproduced or distributed pursuant to this agreement that include Intellectual Property made, conceived, derived from, or reduced to practice by Contractor or CDPH and which result directly or indirectly from this agreement, shall include CDPH's notice of copyright, which shall read in 3mm or larger typeface: "© [Enter Current Year e.g., 2006, etc.], California Department of Public Health. This material may not be reproduced or disseminated without prior written permission from the California Department of Public Health." This notice should be placed prominently on the materials and set apart from other matter on the page where it appears. Audio productions shall contain a similar audio notice of copyright.

**d. Patent Rights**

With respect to inventions made by Contractor in the performance of this agreement, which did not result from research and development specifically included in the agreement's scope of work, Contractor hereby grants to CDPH a license as described under Section b of this provision for devices or material incorporating, or made through the use of such inventions. If such inventions result from research and development work specifically included within the agreement's scope of work, then Contractor agrees to assign to CDPH, without additional compensation, all its right, title and interest in and to such inventions and to assist CDPH in securing United States and foreign patents with respect thereto.

**e. Third-Party Intellectual Property**

Except as provided herein, Contractor agrees that its performance of this agreement shall not be dependent upon or include any Intellectual Property of Contractor or third party without first: (i) obtaining CDPH's prior written approval; and (ii) granting to or obtaining for CDPH, without additional compensation, a license, as described in Section b of this provision, for any of Contractor's or third-party's Intellectual Property in existence prior to the effective date of this agreement. If such a license upon the these terms is unattainable, and CDPH determines that the Intellectual Property should be included in or is required for Contractor's performance of this agreement, Contractor shall obtain a license under terms acceptable to CDPH.

**f. Warranties****(1) Contractor represents and warrants that:**

- (a) It is free to enter into and fully perform this agreement.
- (b) It has secured and will secure all rights and licenses necessary for its performance of this agreement.
- (c) Neither Contractor's performance of this agreement, nor the exercise by either Party of the rights granted in this agreement, nor any use, reproduction, manufacture, sale, offer to sell, import, export, modification, public and private display/performance, distribution, and disposition of the Intellectual Property made, conceived, derived from, or reduced to practice by Contractor or CDPH and which result directly or indirectly from this agreement will infringe upon or violate any Intellectual Property right, non-disclosure obligation, or other proprietary right or interest of any third-party or entity now existing under the laws of, or hereafter existing or issued by, any state, the United States, or any foreign country. There is currently no actual or threatened claim by any such third party based on an alleged violation of any such right by Contractor.
- (d) Neither Contractor's performance nor any part of its performance will violate the right of privacy of, or constitute a libel or slander against any person or entity.
- (e) It has secured and will secure all rights and licenses necessary for Intellectual Property including, but not limited to, consents, waivers or releases from all authors of music or performances used, and talent (radio, television and motion picture talent), owners of any interest in and to real estate, sites, locations, property or props that may be used or shown.
- (f) It has not granted and shall not grant to any person or entity any right that would or might derogate, encumber, or interfere with any of the rights granted to CDPH in this agreement.
- (g) It has appropriate systems and controls in place to ensure that state funds will not be used in the performance of this agreement for the acquisition, operation or maintenance of computer software in violation of copyright laws.
- (h) It has no knowledge of any outstanding claims, licenses or other charges, liens, or encumbrances of any kind or nature whatsoever that could affect in any way Contractor's performance of this agreement.

**(2) CDPH MAKES NO WARRANTY THAT THE INTELLECTUAL PROPERTY RESULTING FROM THIS AGREEMENT DOES NOT INFRINGE UPON ANY PATENT, TRADEMARK, COPYRIGHT OR THE LIKE, NOW EXISTING OR SUBSEQUENTLY ISSUED.**



**g. Intellectual Property Indemnity**

- (1) Contractor shall indemnify, defend and hold harmless CDPH and its licensees and assignees, and its officers, directors, employees, agents, representatives, successors, and users of its products, ("Indemnitees") from and against all claims, actions, damages, losses, liabilities (or actions or proceedings with respect to any thereof), whether or not rightful, arising from any and all actions or claims by any third party or expenses related thereto (including, but not limited to, all legal expenses, court costs, and attorney's fees incurred in investigating, preparing, serving as a witness in, or defending against, any such claim, action, or proceeding, commenced or threatened) to which any of the Indemnitees may be subject, whether or not Contractor is a party to any pending or threatened litigation, which arise out of or are related to (i) the incorrectness or breach of any of the representations, warranties, covenants or agreements of Contractor pertaining to Intellectual Property; or (ii) any Intellectual Property infringement, or any other type of actual or alleged infringement claim, arising out of CDPH's use, reproduction, manufacture, sale, offer to sell, distribution, import, export, modification, public and private performance/display, license, and disposition of the Intellectual Property made, conceived, derived from, or reduced to practice by Contractor or CDPH and which result directly or indirectly from this agreement. This indemnity obligation shall apply irrespective of whether the infringement claim is based on a patent, trademark or copyright registration that issued after the effective date of this agreement. CDPH reserves the right to participate in and/or control, at Contractor's expense, any such infringement action brought against CDPH.
- (2) Should any Intellectual Property licensed by the Contractor to CDPH under this agreement become the subject of an Intellectual Property infringement claim, Contractor will exercise its authority reasonably and in good faith to preserve CDPH's right to use the licensed Intellectual Property in accordance with this agreement at no expense to CDPH. CDPH shall have the right to monitor and appear through its own counsel (at Contractor's expense) in any such claim or action. In the defense or settlement of the claim, Contractor may obtain the right for CDPH to continue using the licensed Intellectual Property; or, replace or modify the licensed Intellectual Property so that the replaced or modified Intellectual Property becomes non-infringing provided that such replacement or modification is functionally equivalent to the original licensed Intellectual Property. If such remedies are not reasonably available, CDPH shall be entitled to a refund of all monies paid under this agreement, without restriction or limitation of any other rights and remedies available at law or in equity.
- (3) Contractor agrees that damages alone would be inadequate to compensate CDPH for breach of any term of this Intellectual Property Exhibit by Contractor. Contractor acknowledges CDPH would suffer irreparable harm in the event of such breach and agrees CDPH shall be entitled to obtain equitable relief, including without limitation an injunction, from a court of competent jurisdiction, without restriction or limitation of any other rights and remedies available at law or in equity.

**h. Federal Funding**

In any agreement funded in whole or in part by the federal government, CDPH may acquire and maintain the Intellectual Property rights, title, and ownership, which results directly or indirectly from the agreement; except as provided in 37 Code of Federal Regulations part 401.14; however, the federal government shall have a non-exclusive, nontransferable, irrevocable, paid-up license throughout the world to use, duplicate, or dispose of such Intellectual Property throughout the world in any manner for governmental purposes and to have and permit others to do so.

**i. Survival**

The provisions set forth herein shall survive any termination or expiration of this agreement or any project schedule.

**9. Prior Approval of Training Seminars, Workshops or Conferences**

Contractor shall obtain prior CDPH approval of the location, costs, dates, agenda, instructors, instructional materials, and attendees at any reimbursable training seminar, workshop, or conference conducted pursuant to this agreement and of any reimbursable publicity or educational materials to be made available for distribution. The Contractor shall acknowledge the support of the State whenever publicizing the work under this agreement in any media. This provision does not apply to necessary staff meetings or training sessions held for the staff of the Contractor or Subcontractor to conduct routine business matters.

**10. Confidentiality of Information**

- a. The Contractor and its employees, agents, or subcontractors shall protect from unauthorized disclosure names and other identifying information concerning persons either receiving services pursuant to this agreement or persons whose names or identifying information become available or are disclosed to the Contractor, his/her employees, agents, or subcontractors as a result of services performed under this agreement, except for statistical information not identifying any such person.
- b. The Contractor and its employees, agents, or subcontractors shall not use such identifying information for any purpose other than carrying out the Contractor's obligations under this agreement.
- c. The Contractor and its employees, agents, or subcontractors shall promptly transmit to the CDPH program contract manager all requests for disclosure of such identifying information not emanating from the client or person.
- d. The Contractor shall not disclose, except as otherwise specifically permitted by this agreement or authorized by the client, any such identifying information to anyone other than CDPH without prior written authorization from the CDPH program contract manager, except if disclosure is required by State or Federal law.
- e. For purposes of this provision, identity shall include, but not be limited to name, identifying number, symbol, or other identifying particular assigned to the individual, such as finger or voice print or a photograph.

**11. Documents, Publications and Written Reports**

(Applicable to agreements over \$5,000 under which publications, written reports and documents are developed or produced. Government Code Section 7550.)

Any document, publication or written report (excluding progress reports, financial reports and normal contract communications) prepared as a requirement of this agreement shall contain, in a separate section preceding the main body of the document, the number and dollar amounts of all contracts and subcontracts relating to the preparation of such document or report, if the total cost for work by nonemployees of the State exceeds \$5,000.

**12. Dispute Resolution Process**

- a. A Contractor grievance exists whenever there is a dispute arising from CDPH's action in the administration of an agreement. If there is a dispute or grievance between the Contractor and CDPH, the Contractor must seek resolution using the procedure outlined below.
  - (1) The Contractor should first informally discuss the problem with the CDPH program contract manager. If the problem cannot be resolved informally, the Contractor shall direct its grievance together with any evidence, in writing, to the program Branch Chief. The grievance shall state the issues in dispute, the legal authority or other basis for the Contractor's position and the remedy sought. The Branch Chief shall render a decision within ten (10) working days after receipt of the written grievance from the Contractor. The Branch Chief shall respond in writing to the Contractor indicating the decision and reasons therefore. Should

the Contractor disagree with the Branch Chief's decision, the Contractor may appeal to the second level.

- (2) When appealing to the second level, the Contractor must prepare an appeal indicating the reasons for disagreement with Branch Chief's decision. The Contractor shall include with the appeal a copy of the Contractor's original statement of dispute along with any supporting evidence and a copy of the Branch Chief's decision. The appeal shall be addressed to the Deputy Director of the division in which the branch is organized within ten (10) working days from receipt of the Branch Chief's decision. The Deputy Director of the division in which the branch is organized or his/her designee shall meet with the Contractor to review the issues raised. A written decision signed by the Deputy Director of the division in which the branch is organized or his/her designee shall be directed to the Contractor within twenty (20) working days of receipt of the Contractor's second level appeal.
- b. If the Contractor wishes to appeal the decision of the Deputy Director of the division in which the branch is organized or his/her designee, the Contractor shall follow the procedures set forth in Division 25.1 (commencing with Section 38050) of the Health and Safety Code and the regulations adopted thereunder. (Title 1, Subchapter 2.5, commencing with Section 251, California Code of Regulations.)
- c. Disputes arising out of an audit, examination of an agreement or other action not covered by subdivision (a) of Section 20204, of Chapter 2.1, Title 22, of the California Code of Regulations, and for which no procedures for appeal are provided in statute, regulation or the agreement, shall be handled in accordance with the procedures identified in Sections 51016 through 51047, Title 22, California Code of Regulations.
- d. Unless otherwise stipulated in writing by CDPH, all dispute, grievance and/or appeal correspondence shall be directed to the CDPH program contract manager.
- e. There are organizational differences within CDPH' funding programs and the management levels identified in this dispute resolution provision may not apply in every contractual situation. When a grievance is received and organizational differences exist, the Contractor shall be notified in writing by the CDPH program contract manager of the level, name, and/or title of the appropriate management official that is responsible for issuing a decision at a given level.

### 13. Financial and Compliance Audit Requirements

- a. The definitions used in this provision are contained in Section 38040 of the Health and Safety Code, which by this reference is made a part hereof.
- b. Direct service contract means a contract for services contained in local assistance or subvention programs or both (see Health and Safety [H&S] Code section 38020). Direct service contracts shall not include contracts, grants, or subventions to other governmental agencies or units of government nor contracts with regional centers or area agencies on aging (See H&S Code section 38030).
- c. The Contractor, as indicated below, agrees to obtain one of the following audits:
  - (1) If the Contractor is a nonprofit organization (as defined in H&S Code section 38040) and receives \$25,000 or more from any State agency under a direct service contract: the Contractor agrees to obtain an annual single, organization wide, financial and compliance audit. Said audit shall be conducted according to Generally Accepted Auditing Standards. This audit does not fulfill the audit requirements of Paragraph c(3) below. The audit shall be completed by the 15th day of the fifth month following the end of the Contractor's fiscal year, and/or
  - (2) If the Contractor is a nonprofit organization (as defined in H&S Code section 38040) and receives less than \$25,000 per year from any State agency under a direct service contract, the Contractor agrees to obtain a biennial single, organization wide financial and compliance audit, unless there is evidence of fraud or other violation of state law in connection with this

agreement. This audit does not fulfill the audit requirements of Paragraph c(3) below. The audit shall be completed by the 15th day of the fifth month following the end of the Contractor's fiscal year, and/or

- (3) If the Contractor is a State or Local Government entity or Nonprofit organization (as defined by the Federal Office of Management and Budget [OMB] Circular A-133) and expends \$500,000 or more in Federal awards, the Contractor agrees to obtain an annual single, organization wide, financial and compliance audit according to the requirements specified in OMB Circular A-133 entitled "Audits of States, Local Governments, and Non-Profit Organizations". An audit conducted pursuant to this provision will fulfill the audit requirements outlined in Paragraphs c(1) and c(2) above. The audit shall be completed by the end of the ninth month following the end of the audit period. The requirements of this provision apply if:
- (a) The Contractor is a recipient expending Federal awards received directly from Federal awarding agencies, or
  - (b) The Contractor is a subrecipient expending Federal awards received from a pass-through entity such as the State, County or community based organization.
- (4) If the Contractor submits to CDPH a report of an audit other than an OMB A-133 audit, the Contractor must also submit a certification indicating the Contractor has not expended \$500,000 or more in federal funds for the year covered by the audit report.
- d. Two copies of the audit report shall be delivered to the CDPH program funding this agreement. The audit report must identify the Contractor's legal name and the number assigned to this agreement. The audit report shall be due within 30 days after the completion of the audit. Upon receipt of said audit report, the CDPH program contract manager shall forward the audit report to CDPH's Audits and Investigations Unit if the audit report was submitted under Section 13C(3), unless the audit report is from a City, County, or Special District within the State of California whereby the report will be retained by the funding program.
  - e. The cost of the audits described herein may be included in the funding for this agreement up to the proportionate amount this agreement represents of the Contractor's total revenue. The CDPH program funding this agreement must provide advance written approval of the specific amount allowed for said audit expenses.
  - f. The State or its authorized designee, including the Bureau of State Audits, is responsible for conducting agreement performance audits which are not financial and compliance audits. Performance audits are defined by Generally Accepted Government Auditing Standards.
  - g. Nothing in this agreement limits the State's responsibility or authority to enforce State law or regulations, procedures, or reporting requirements arising thereto.
  - h. Nothing in this provision limits the authority of the State to make audits of this contract, provided however, that if independent audits arranged for by the Contractor meet Generally Accepted Governmental Auditing Standards, the State shall rely on those audits and any additional audit work and shall build upon the work already done.
  - i. The State may, at its option, direct its own auditors to perform either of the audits described above. The Contractor will be given advance written notification, if the State chooses to exercise its option to perform said audits.

#### 14. Novation Requirements

If the Contractor proposes any novation agreement, CDPH shall act upon the proposal within 60 days after receipt of the written proposal. CDPH may review and consider the proposal, consult and negotiate with the Contractor, and accept or reject all or part of the proposal. Acceptance or rejection of the proposal may be made orally within the 60-day period and confirmed in writing within five days of said decision. Upon written acceptance of the proposal, CDPH will initiate an amendment to this

agreement to formally implement the approved proposal.

**15. Payment Withholds**

(Applicable only if a final report is required by this agreement. Not applicable to government entities.)

Unless waived or otherwise stipulated in this agreement, CDPH may, at its discretion, withhold 10 percent (10%) of the face amount of the contract, 50 percent (50%) of the final invoice, or \$3,000 whichever is greater, until CDPH receives a final report that meets the terms, conditions and/or scope of work requirements of this agreement.

**16. Performance Evaluation**

(Not applicable to grant agreements.)

CDPH may, at its discretion, evaluate the performance of the Contractor at the conclusion of this agreement. If performance is evaluated, the evaluation shall not be a public record and shall remain on file with CDPH. Negative performance evaluations may be considered by CDPH prior to making future contract awards.

**17. Officials Not to Benefit**

No members of or delegate of Congress or the State Legislature shall be admitted to any share or part of this agreement, or to any benefit that may arise therefrom. This provision shall not be construed to extend to this agreement if made with a corporation for its general benefits.

**18. Four-Digit Date Compliance**

(Applicable to agreements in which Information Technology (IT) services are provided to CDPH or if IT equipment is procured.)

Contractor warrants that it will provide only Four-Digit Date Compliant. Deliverables and/or services to the State. "Four Digit Date compliant" Deliverables and services can accurately process, calculate, compare, and sequence date data, including without limitation date data arising out of or relating to leap years and changes in centuries. This warranty and representation is subject to the warranty terms and conditions of this Contract and does not limit the generality of warranty obligations set forth elsewhere herein.

**19. Union Organizing**

(Applicable only to grant agreements.)

Grantee, by signing this agreement, hereby acknowledges the applicability of Government Code 16645 through 16649 to this agreement. Furthermore, Grantee, by signing this agreement, hereby certifies that:

- a. No state funds disbursed by this grant will be used to assist, promote or deter union organizing.
- b. Grantee shall account for state funds disbursed for a specific expenditure by this grant, to show those funds were allocated to that expenditure.
- c. Grantee shall, where state funds are not designated as described in b herein, allocate, on a pro-rata basis, all disbursements that support the grant program.
- d. If Grantee makes expenditures to assist, promote or deter union organizing, Grantee will maintain records sufficient to show that no state funds were used for those expenditures, and that Grantee shall provide those records to the Attorney General upon request.

**20. Contract Uniformity (Fringe Benefit Allowability)**

(Applicable only to nonprofit organizations.)

Pursuant to the provisions of Article 7 (commencing with Section 100525) of Chapter 3 of Part 1 of Division 101 of the Health and Safety Code, CDPH sets forth the following policies, procedures, and guidelines regarding the reimbursement of fringe benefits.

- a. As used herein fringe benefits shall mean an employment benefit given by one's employer to an employee in addition to one's regular or normal wages or salary.
- b. As used herein, fringe benefits do not include:
  - (1) Compensation for personal services paid currently or accrued by the Contractor for services of employees rendered during the term of this agreement, which is identified as regular or normal salaries and wages, annual leave, vacation, sick leave, holidays, jury duty and/or military leave/training.
  - (2) Director's and executive committee member's fees.
  - (3) Incentive awards and/or bonus incentive pay.
  - (4) Allowances for off-site pay.
  - (5) Location allowances.
  - (6) Hardship pay.
  - (7) Cost-of-living differentials
- c. Specific allowable fringe benefits include:
  - (1) Fringe benefits in the form of employer contributions for the employer's portion of payroll taxes (i.e., FICA, SUI, SDI), employee health plans (i.e., health, dental and vision), unemployment insurance, worker's compensation insurance, and the employer's share of pension/retirement plans, provided they are granted in accordance with established written organization policies and meet all legal and Internal Revenue Service requirements.
- d. To be an allowable fringe benefit, the cost must meet the following criteria:
  - (1) Be necessary and reasonable for the performance of the agreement.
  - (2) Be determined in accordance with generally accepted accounting principles.
  - (3) Be consistent with policies that apply uniformly to all activities of the Contractor.
- e. Contractor agrees that all fringe benefits shall be at actual cost.
- f. Earned/Accrued Compensation
  - (1) Compensation for vacation, sick leave and holidays is limited to that amount earned/accrued within the agreement term. Unused vacation, sick leave and holidays earned from periods prior to the agreement term cannot be claimed as allowable costs. See Provision f (3)(a) for an example.
  - (2) For multiple year contracts, vacation and sick leave compensation, which is earned/accrued but not paid, due to employee(s) not taking time off may be carried over and claimed within the overall term of the multiple years of the agreement. Holidays cannot be carried over from one contract year to the next. See f Provision (3)(b) for an example.
  - (3) For single year agreements, vacation, sick leave and holiday compensation that is earned/accrued but not paid, due to employee(s) not taking time off within the term of the agreement, cannot be claimed as an allowable cost. See Provision f (3)(c) for an example.

**(a) Example No. 1:**

If an employee, John Doe, earns/accrues three weeks of vacation and twelve days of sick leave each year, then that is the maximum amount that may be claimed during a

contract period of one year. If John Doe has five weeks of vacation and eighteen days of sick leave at the beginning of the agreement, the Contractor during a one-year agreement term may only claim up to three weeks of vacation and twelve days of sick leave actually used by the employee. Amounts earned/accrued in periods prior to the beginning of the agreement are not an allowable cost.

**(b) Example No. 2:**

If during a three-year (multiple year) agreement, John Doe does not use his three weeks of vacation in year one, or his three weeks in year two, but he does actually use nine weeks in year three; the Contractor would be allowed to claim all nine weeks paid for in year three. The total compensation over the three-year period cannot exceed 156 weeks (3 x 52 weeks).

**(c) Example No. 3:**

If during a single year agreement, John Doe works fifty weeks and used one week of vacation and one week of sick leave and all fifty-two weeks have been billed to CDPH, the remaining unused two weeks of vacation and seven days of sick leave may not be claimed as an allowable cost.

**Exhibit E**  
**Additional Provisions**

**1. Amendment Process**

Should either party, during the term of this agreement, desire a change or amendment to the terms of this Agreement, such changes or amendments shall be proposed in writing to the other party, who will respond in writing as to whether the proposed changes/amendments are accepted or rejected. If accepted and after negotiations are concluded, the agreed upon changes shall be made through the State's official agreement amendment process. No amendment will be considered binding on either party until it is formally approved by the State.

**2. Cancellation / Termination**

- A. This agreement may be cancelled or terminated without cause by either party by giving thirty (30) calendar days advance written notice to the other party. Such notification shall state the effective date of termination or cancellation and include any final performance and/or payment/invoicing instructions/requirements.
- B. Upon receipt of a notice of termination or cancellation from CDPH, Contractor shall take immediate steps to stop performance and to cancel or reduce subsequent contract costs.
- C. Contractor shall be entitled to payment for all allowable costs authorized under this agreement, including authorized non-cancelable obligations incurred up to the date of termination or cancellation, provided such expenses do not exceed the stated maximum amounts payable.

**3. Avoidance of Conflicts of Interest by Contractor**

- A. CDPH intends to avoid any real or apparent conflict of interest on the part of the Contractor, subcontractors, or employees, officers and directors of the Contractor or subcontractors. Thus, CDPH reserves the right to determine, at its sole discretion, whether any information, assertion or claim received from any source indicates the existence of a real or apparent conflict of interest; and, if a conflict is found to exist, to require the Contractor to submit additional information or a plan for resolving the conflict, subject to CDPH review and prior approval.
- B. Conflicts of interest include, but are not limited to:
  - 1) An instance where the Contractor or any of its subcontractors, or any employee, officer, or director of the Contractor or any subcontractor has an interest, financial or otherwise, whereby the use or disclosure of information obtained while performing services under the contract would allow for private or personal benefit or for any purpose that is contrary to the goals and objectives of the contract.
  - 2) An instance where the Contractor's or any subcontractor's employees, officers, or directors use their positions for purposes that are, or give the appearance of being, motivated by a desire for private gain for themselves or others, such as those with whom they have family, business or other ties.
- C. If CDPH is or becomes aware of a known or suspected conflict of interest, the Contractor will be given an opportunity to submit additional information or to resolve the conflict. A Contractor with a suspected conflict of interest will have five (5) working days from the date of notification of the conflict by CDPH to provide complete information regarding the suspected conflict.



**Exhibit E**  
**Additional Provisions**

If a conflict of interest is determined to exist by CDPH and cannot be resolved to the satisfaction of CDPH, the conflict will be grounds for terminating the contract.

CDPH may, at its discretion upon receipt of a written request from the Contractor, authorize an extension of the timeline indicated herein.

**4. Insurance Requirements**

Contractor shall comply with the following insurance requirements:

**A. Commercial General Liability**

The Contractor must furnish to CDPH a certificate of insurance stating that commercial general liability insurance of not less than \$1,000,000 per occurrence for bodily injury and property damage liability combined is presently in effect for the Contractor. The commercial general liability insurance policy shall include coverage for liabilities arising out of premises, operations, independent contractors, products, completed operations, personal and advertising injury, and liability assumed under an insured agreement. The commercial general liability insurance shall apply separately to each insured against whom claim is made or suit is brought subject to the Contractor's limit of liability.

**B. The certificate of insurance must identify the agreement number for which the certificate of insurance applies and include the following provisions:**

- 1) The insurer will not cancel the insured's coverage without giving 30 days prior written notice to the California Department of Public Health, and
- 2) The State of California, its officers, agents, employees, and servants are included as additional insureds, but only with respect to work performed for the State of California under this agreement.

**C. The Contractor agrees that the insurance required herein will remain in effect at all times during the term of the agreement. In the event said insurance coverage expires at any time or times during the term of this agreement, the Contractor agrees to provide, at least 30 calendar days before said expiration date, a new certificate of insurance evidencing insurance coverage as provided for herein for not less than the remainder of the term of the agreement or for a period of not less than one year. CDPH may, in addition to any other remedies it may have, terminate this agreement on the occurrence of such event.**

**D. CDPH will not be responsible for any premiums, deductibles, or assessments on the insurance policy.**

## Contractor's Release

### Instructions to Contractor:

With final invoice(s) submit one (1) original and one (1) copy. The original must bear the original signature of a person authorized to bind the Contractor. The additional copy may bear photocopied signatures.

### Submission of Final Invoice

Pursuant to contract number \_\_\_\_\_ entered into between the California Department of Public Health (CDPH) and the Contractor (identified below), the Contractor does acknowledge that final payment has been requested via invoice number(s) \_\_\_\_\_, in the amount(s) of \$ \_\_\_\_\_ and dated \_\_\_\_\_.  
If necessary, enter "See Attached" in the appropriate blocks and attach a list of invoice numbers, dollar amounts and invoice dates.

### Release of all Obligations

By signing this form, and upon receipt of the amount specified in the invoice number(s) referenced above, the Contractor does hereby release and discharge the State, its officers, agents and employees of and from any and all liabilities, obligations, claims, and demands whatsoever arising from the above referenced contract.

### Repayments Due to Audit Exceptions / Record Retention

By signing this form, Contractor acknowledges that expenses authorized for reimbursement does not guarantee final allowability of said expenses. Contractor agrees that the amount of any sustained audit exceptions resulting from any subsequent audit made after final payment will be refunded to the State.

All expense and accounting records related to the above referenced contract must be maintained for audit purposes for no less than three years beyond the date of final payment, unless a longer term is stated in said contract.

### Recycled Product Use Certification

By signing this form, Contractor certifies under penalty of perjury that a minimum of 0% unless otherwise specified in writing of post consumer material, as defined in the Public Contract Code Section 12200, in products, materials, goods, or supplies offered or sold to the State regardless of whether it meets the requirements of Public Contract Code Section 12209. Contractor specifies that printer or duplication cartridges offered or sold to the State comply with the requirements of Section 12156(e).

### Reminder to Return State Equipment/Property (If Applicable)

(Applies only if equipment was provided by CDPH or purchased with or reimbursed by contract funds)

Unless CDPH has approved the continued use and possession of State equipment (as defined in the above referenced contract) for use in connection with another CDPH agreement, Contractor agrees to promptly initiate arrangements to account for and return said equipment to CDPH, at CDPH's expense, if said equipment has not passed its useful life expectancy as defined in the above referenced contract.

### Patents / Other Issues

By signing this form, Contractor further agrees, in connection with patent matters and with any claims that are not specifically released as set forth above, that it will comply with all of the provisions contained in the above referenced contract, including, but not limited to, those provisions relating to notification to the State and related to the defense or prosecution of litigation.

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ONLY SIGN AND DATE THIS DOCUMENT WHEN ATTACHING IT TO THE FINAL INVOICE

Contractor's Legal Name (as on contract): \_\_\_\_\_

Signature of Contractor or Official Designee: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name/Title of Person Signing: \_\_\_\_\_

Distribution:      Accounting (Original)      Program

**Exhibit G**  
HIPAA Business Associate Addendum

**I. Recitals – HIGH RISK**

- A. This Contract (Agreement) has been determined to constitute a business associate relationship under the Health Insurance Portability and Accountability Act ("HIPAA") and its implementing privacy and security regulations at 45 CFR Parts 160 and 164 ("the HIPAA regulations:").
- B. The California Department of Health Services ("CDHS") wishes to disclose to Business Associate certain information pursuant to the terms of this Agreement, some of which may constitute Protected Health Information ("PHI").
- C. "Protected Health Information" or "PHI" means any information, whether oral or recorded in any form or medium that relates to the past, present, or future physical or mental condition of an individual, the provision of health and dental care to an individual, or the past, present, or future payment for the provision of health and dental care to an individual; and that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual. PHI shall have the meaning given to such term under HIPAA and HIPAA regulations, as the same may be amended from time to time.
- D. "Security Incident" means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of PHI, or confidential data that is essential to the ongoing operation of the Business Associate's organization and intended for internal use; or interference with system operations in an information system.
- E. As set forth in this Agreement Contractor, here and after, is the Business Associate of CDPH that provides services, arranges, performs or assists in the performance of functions or activities on behalf of CDPH and creates, receives, maintains, transmits, uses or discloses PHI.
- F. CDPH and Business Associate desire to protect the privacy and provide for the security of PHI created, received, maintained, transmitted, used or disclosed pursuant to this Agreement, in compliance with HIPAA and HIPAA regulations and other applicable laws.
- G. The purpose of the Addendum is to satisfy certain standards and requirements of HIPAA and the HIPAA regulations.
- H. The terms used in this Addendum, but not otherwise defined, shall have the same meanings as those terms in the HIPAA regulations.

In exchanging information pursuant to this Agreement, the parties agree as follows:

**1. Permitted Uses and Disclosures of PHI by Business Associate**

- A. **Permitted Uses and Disclosures.** Except as otherwise indicated in this Addendum, Business Associate may use or disclose PHI only to perform functions, activities or services specified in this Agreement, for, or on behalf of CDPH, provided that such use or disclosure would not violate the HIPAA regulations, if done by CDPH.
- B. **Specific Use and Disclosure Provisions.** Except as otherwise indicated in this Addendum, Business Associate may:
  - 1) **Use and disclose for management and administration.** Use and disclose PHI for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate, provided that disclosures are required by law, or the Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will

**Exhibit G**  
**HIPAA Business Associate Addendum**

remain confidential and will be used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware that the confidentiality of the information has been breached.

- 2) **Provision of Data Aggregation Services.** Use PHI to provide data aggregation services to CDPH. Data aggregation means the combining of PHI created or received by the Business Associate on behalf of CDPH with PHI received by the Business Associate in its capacity as the Business Associate of another covered entity, to permit data analyses that relate to the health care operations of CDPH.

**2. Responsibilities of Business Associate**

Business Associate agrees:

- A. **Nondisclosure.** Not to use or disclose Protected Health Information (PHI) other than as permitted or required by this Agreement or as required by law.
- B. **Safeguards.** To implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the PHI, including electronic PHI, that it creates, receives, maintains, uses or transmits on behalf of CDPH; and to prevent use or disclosure of PHI other than as provided for by this Agreement. Business Associate shall develop and maintain a written information privacy and security program that includes administrative, technical and physical safeguards appropriate to the size and complexity of the Business Associate's operations and the nature and scope of its activities, and which incorporates the requirements of section C, Security, below. Business Associate will provide CDPH with its current and updated policies.
- C. **Security.** To take any and all steps necessary to ensure the continuous security of all computerized data systems containing PHI, and provide data security procedures for the use of CDPH at the end of the contract period. These steps shall include, at a minimum:
- 1) Complying with all of the data system security precautions listed in this Agreement or in an Exhibit attached to this Agreement;
  - 2) Achieving and maintaining compliance with the HIPAA Security Rule (45 CFR Parts 160 and 164), as necessary in conducting operations on behalf of CDPH under this Agreement;
  - 3) Providing a level and scope of security that is at least comparable to the level and scope of security established by the Office of Management and Budget in OMB Circular No. A-130, Appendix III- Security of Federal Automated Information Systems, which sets forth guidelines for automated information systems in Federal agencies; and
  - 4) Complying with the safeguard provisions in the Department's Information Security Policy, embodied in Health Administrative Manual (HAM), sections 6-1000 et seq. and in the Security and Risk Management Policy in the Information Technology Section of the State Administrative Manual (SAM), sections 4840 et seq., in so far as the security standards in these manuals apply to Business Associate's operations. In case of a conflict between any of the security standards contained in any of these four enumerated sources of security standards, the most stringent shall apply. The most stringent means that safeguard which provides the highest level of protection to PHI from unauthorized disclosure. Further, Business Associate must comply with changes to these standards that occur after the effective date of this Agreement.

Business Associate shall designate a Security Officer to oversee its data security program who shall be responsible for carrying out the requirements of this section and for communicating on security matters with CDPH.

**Exhibit G**  
**HIPAA Business Associate Addendum**

- D. **Mitigation of Harmful Effects.** To mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate or its subcontractors in violation of the requirements of this Addendum.
- E. **Business Associate's Agents.** To ensure that any agents, including subcontractors, to whom Business Associate provides PHI received from or created or received by Business Associate on behalf of CDPH, agree to the same restrictions and conditions that apply to Business Associate with respect to such PHI, including implementation of reasonable and appropriate administrative, physical, and technical safeguards to protect such PHI; and to incorporate, when applicable, the relevant provisions of this Addendum into each subcontract or subaward to such agents or subcontractors.
- F. **Availability of Information to CDPH and Individuals.** To provide access as CDPH may require, and in the time and manner designated by CDPH (upon reasonable notice and during Business Associate's normal business hours) to PHI in a Designated Record Set, to CDPH (or, as directed by CDPH), to an Individual, in accordance with 45 CFR Section 164.524. Designated Record Set means the group of records maintained for CDPH that includes medical, dental and billing records about individuals; enrollment, payment, claims adjudication, and case or medical management systems maintained for CDPH health plans; or those records used to make decisions about individuals on behalf of CDPH. Business Associate shall use the forms and processes developed by CDPH for this purpose and shall respond to requests for access to records transmitted by CDPH within fifteen (15) calendar days of receipt of the request by producing the records or verifying that there are none.
- G. **Amendment of PHI.** To make any amendment(s) to PHI that CDPH directs or agrees to pursuant to 45 CFR Section 164.526, in the time and manner designated by CDPH.
- H. **Internal Practices.** To make Business Associate's internal practices, books and records relating to the use and disclosure of PHI received from CDPH, or created or received by Business Associate on behalf of CDPH, available to CDPH or to the Secretary of the U.S. Department of Health and Human Services in a time and manner designated by CDPH or by the Secretary, for purposes of determining CDPH's compliance with the HIPAA regulations.
- I. **Documentation of Disclosures.** To document and make available to CDPH or (at the direction of CDPH) to an Individual such disclosures of PHI, and information related to such disclosures, necessary to respond to a proper request by the subject Individual for an accounting of disclosures of PHI, in accordance with 45 CFR 164.528.
- J. **Notification of Breach.** During the term of this Agreement:
- 1) **Discovery of Breach.** To notify CDPH **immediately by telephone call plus e-mail or fax** upon the discovery of breach of security of PHI in computerized form if the PHI was, or is reasonably believed to have been, acquired by an unauthorized person; or **within 24 hours by e-mail or fax** of any suspected security incident, intrusion or unauthorized use or disclosure of PHI in violation of this Agreement and this Addendum, or potential loss of confidential data affecting this Agreement. Notification shall be provided to the CDPH contract manager, the CDPH Privacy Officer and the CDPH Information Security Officer. If the incident occurs after business hours or on a weekend or holiday and involves electronic PHI, notification shall be provided by calling the CDPH ITSD Help Desk. Business Associate shall take:
    - i. Prompt corrective action to mitigate any risks or damages involved with the breach and to protect the operating environment and
    - ii. Any action pertaining to such unauthorized disclosure required by applicable Federal and State laws and regulations.

**Exhibit G**  
**HIPAA Business Associate Addendum**

- 2) **Investigation of Breach.** To immediately investigate such security incident, breach, or unauthorized use or disclosure of PHI or confidential data. Within 72 hours of the discovery, to notify the CDPH contract manager, the CDPH Privacy Officer, and the CDPH Information Security Officer of:
- What data elements were involved and the extent of the data involved in the breach,
  - A description of the unauthorized persons known or reasonably believed to have improperly used or disclosed PHI or confidential data,
  - A description of where the PHI or confidential data is believed to have been improperly transmitted, sent, or utilized,
  - A description of the probable causes of the improper use or disclosure; and
  - Whether Civil Code sections 1798.29 or 1798.82 or any other federal or state laws requiring individual notifications of breaches are triggered.
- 3) **Written Report.** To provide a written report of the investigation to the CDPH contract manager, the CDPH Privacy Officer, and the CDPH Information Security Officer within ten (10) working days of the discovery of the breach or unauthorized use or disclosure. The report shall include, but not be limited to, the information specified above, as well as a full, detailed corrective action plan, including information on measures that were taken to halt and/or contain the improper use or disclosure.
- 4) **Notification of Individuals.** To notify individuals of the breach or unauthorized use or disclosure when required under state or federal law and to pay any costs of such notifications, as well as any costs associated with the breach. The CDPH contract manager, the CDPH Privacy Officer, and the CDPH Information Security Officer shall approve the time, manner and content of any such notifications.
- 5) **CDPH Contact Information.** To direct communications to the above referenced CDPH staff, the Contractor shall initiate contact as indicated herein. CDPH reserves the right to make changes to the contact information below by giving written notice to the Contractor. Said changes shall not require an amendment to this Agreement or Addendum.

<b>CDPH Contract Manager</b>	<b>CDPH Privacy Officer</b>	<b>CDPH Information Security Officer</b>
See Provision 4 of Exhibit A for Contract Manager information or other applicable contract section	Privacy Officer c/o: Office of Legal Services California Department of Health Services P.O. Box 997413, MS 0011 Sacramento, CA 95899-7413 Telephone: (916) 440-7750 Email: <a href="mailto:privacyofficer@dhs.ca.gov">privacyofficer@dhs.ca.gov</a>	Information Security Officer Information Security Office P.O. Box 997413, MS 6302 Sacramento, CA 95899-7413 Email: <a href="mailto:dhsiso@dhs.ca.gov">dhsiso@dhs.ca.gov</a> Telephone: ITSD Help Desk 916-440-7000 or 800-579-0874

- K. **Employee Training and Discipline.** To train and use reasonable measures to ensure compliance with the requirements of this Addendum by employees who assist in the performance of functions or activities on behalf of CDPH under this Agreement and use or disclose PHI; and discipline such employees who intentionally violate any provisions of this Addendum, including by termination of employment.

**Exhibit G**  
**HIPAA Business Associate Addendum**

**3. Obligations of CDPH**

CDPH agrees to:

- A. **Notice of Privacy Practices.** Provide Business Associate with the Notice of Privacy Practices that CDPH produces in accordance with 45 CFR 164.520, as well as any changes to such notice. Visit this Internet address to view the most current Notice of Privacy Practices: <http://www.dhs.ca.gov/hipaa>.
- B. **Permission by Individuals for Use and Disclosure of PHI.** Provide the Business Associate with any changes in, or revocation of, permission by an Individual to use or disclose PHI, if such changes affect the Business Associate's permitted or required uses and disclosures.
- C. **Notification of Restrictions.** Notify the Business Associate of any restriction to the use or disclosure of PHI that CDPH has agreed to in accordance with 45 CFR 164.522, to the extent that such restriction may affect the Business Associate's use or disclosure of PHI.
- D. **Requests Conflicting with HIPAA Rules.** Not request the Business Associate to use or disclose PHI in any manner that would not be permissible under the HIPAA regulations if done by CDPH.

**4. Audits, Inspection and Enforcement**

From time to time, CDPH may inspect the facilities, systems, books and records of Business Associate to monitor compliance with this Agreement and this Addendum. Business Associate shall promptly remedy any violation of any provision of this Addendum and shall certify the same to the CDPH Privacy Officer in writing. The fact that CDPH inspects, or fails to inspect, or has the right to inspect, Business Associate's facilities, systems and procedures does not relieve Business Associate of its responsibility to comply with this Addendum, nor does CDPH's:

- A. Failure to detect or
- B. Detection, but failure to notify Business Associate or require Business Associate's remediation of any unsatisfactory practices constitute acceptance of such practice or a waiver of CDPH's enforcement rights under this Agreement and this Addendum.

**5. Termination**

- A. **Termination for Cause.** Upon CDPH's knowledge of a material breach of this Addendum by Business Associate, CDPH shall:
  - 1) Provide an opportunity for Business Associate to cure the breach or end the violation and terminate this Agreement if Business Associate does not cure the breach or end the violation within the time specified by CDPH;
  - 2) Immediately terminate this Agreement if Business Associate has breached a material term of this Addendum and cure is not possible; or
  - 3) If neither cure nor termination is feasible, report the violation to the Secretary of the U.S. Department of Health and Human Services.
- B. **Judicial or Administrative Proceedings.** Business Associate will notify CDPH if it is named as a defendant in a criminal proceeding for a violation of HIPAA. CDPH may terminate this Agreement if Business Associate is found guilty of a criminal violation of HIPAA. CDPH may terminate this Agreement if a finding or stipulation that the Business Associate has violated any standard or

**Exhibit G**  
**HIPAA Business Associate Addendum**

requirement of HIPAA, or other security or privacy laws is made in any administrative or civil proceeding in which the Business Associate is a party or has been joined.

- C. **Effect of Termination.** Upon termination or expiration of this Agreement for any reason, Business Associate shall return or destroy all PHI received from CDPH (or created or received by Business Associate on behalf of CDPH) that Business Associate still maintains in any form, and shall retain no copies of such PHI or, if return or destruction is not feasible, shall continue to extend the protections of this Addendum to such information, and shall limit further use of such PHI to those purposes that make the return or destruction of such PHI infeasible. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate.

**6. Miscellaneous Provisions**

- A. **Disclaimer.** CDPH makes no warranty or representation that compliance by Business Associate with this Addendum, HIPAA or the HIPAA regulations will be adequate or satisfactory for Business Associate's own purposes or that any information in Business Associate's possession or control, or transmitted or received by Business Associate, is or will be secure from unauthorized use or disclosure. Business Associate is solely responsible for all decisions made by Business Associate regarding the safeguarding of PHI.
- B. **Amendment.** The parties acknowledge that federal and state laws relating to electronic data security and privacy are rapidly evolving and that amendment of this Addendum may be required to provide for procedures to ensure compliance with such developments. The parties specifically agree to take such action as is necessary to implement the standards and requirements of HIPAA, the HIPAA regulations and other applicable laws relating to the security or privacy of PHI. Upon CDPH's request, Business Associate agrees to promptly enter into negotiations with CDPH concerning an amendment to this Addendum embodying written assurances consistent with the standards and requirements of HIPAA, the HIPAA regulations or other applicable laws. CDPH may terminate this Agreement upon thirty (30) days written notice in the event:
- 1) Business Associate does not promptly enter into negotiations to amend this Addendum when requested by CDPH pursuant to this Section or
  - 2) Business Associate does not enter into an amendment providing assurances regarding the safeguarding of PHI that CDPH in its sole discretion, deems sufficient to satisfy the standards and requirements of HIPAA and the HIPAA regulations.
- C. **Assistance in Litigation or Administrative Proceedings.** Business Associate shall make itself and any subcontractors, employees or agents assisting Business Associate in the performance of its obligations under this Agreement, available to CDPH at no cost to CDPH to testify as witnesses, or otherwise, in the event of litigation or administrative proceedings being commenced against CDPH, its directors, officers or employees based upon claimed violation of HIPAA, the HIPAA regulations or other laws relating to security and privacy, which involves inactions or actions by the Business Associate, except where Business Associate or its subcontractor, employee or agent is a named adverse party.
- D. **No Third-Party Beneficiaries.** Nothing express or implied in the terms and conditions of this Addendum is intended to confer, nor shall anything herein confer, upon any person other than CDPH or Business Associate and their respective successors or assignees, any rights, remedies, obligations or liabilities whatsoever.



**Exhibit G**  
HIPAA Business Associate Addendum

- E. **Interpretation.** The terms and conditions in this Addendum shall be interpreted as broadly as necessary to implement and comply with HIPAA, the HIPAA regulations and applicable state laws. The parties agree that any ambiguity in the terms and conditions of this Addendum shall be resolved in favor of a meaning that complies and is consistent with HIPAA and the HIPAA regulations.
- F. **Regulatory References.** A reference in the terms and conditions of this Addendum to a section in the HIPAA regulations means the section as in effect or as amended.
- G. **Survival.** The respective rights and obligations of Business Associate under Section 6.C of this Addendum shall survive the termination or expiration of this Agreement.
- H. **No Waiver of Obligations.** No change, waiver or discharge of any liability or obligation hereunder on any one or more occasions shall be deemed a waiver of performance of any continuing or other obligation, or shall prohibit enforcement of any obligation, on any other occasion.